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In The

Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-81 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996), both the United States Court of Appeals for the Federal Circuit and this Court endorsed an approach to claim construction in patent cases that looks first and principally to the "intrinsic evidence" (i.e., the patent's claim language, specification, and prosecution history) to determine the meaning of a disputed claim term. But despite *Markman's* effort to achieve "intrajurisdictional certainty" in this critical area of patent law, various panels of the Federal Circuit have continued to use starkly different approaches to claim construction – differences noted with increasing frequency by practitioners, by commentators,[1] and by members of the Federal Circuit itself.[2]

Under one approach, and in concert with *Markman*, some panels of the Federal Circuit rely heavily on a patent's intrinsic evidence to construe disputed claim terms. Under a competing approach, and contrary to *Markman*, some panels look first and principally to "extrinsic" dictionary definitions to determine a disputed term's "ordinary meaning," and consult the intrinsic evidence only to determine if it contains a "manifest exclusion or

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[1] *See, e.g.*, Russell B. Hill and Frank P. Cote, *Ending The Federal Circuit Crapshoot: Emphasizing Plain Meaning In Patent Claim Interpretation*, 42 IDEA: The Journal of Law and Technology 1 (2002) ("Federal Circuit ... cases manifest a palpable inter-panel tension ..."); R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 University of Pennsylvania Law Review 1105 (2004).

[2] *See, e.g.*, *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 898 (Fed. Cir. 2004) (concurrence by Michel, J.)

QUESTIONS PRESENTED – Continued

restriction" of that "ordinary meaning." Moreover, the selection of one approach or the other is of more than academic concern – it can be outcome determinative as was true in the claim construction dispute here.

The Federal Circuit has not, despite repeated opportunities, reconciled these conflicting precedents in an *en banc* sitting. Instead, it appears to be content with what one of its members has characterized as "absurd" results[3] and with continuing, well-documented, and very costly confusion among practitioners and district courts. Indeed, the situation has become so chaotic that, in one recent 10-month period, the Federal Circuit reversed an astounding 74% of district court decisions on claim construction.[4]

The questions presented therefore are:

1) Whether the outcome determinative "intracircuit split" within the Federal Circuit on patent claim construction should be resolved to eliminate the current unpredictable and inefficient legal environment and promote the "intrajurisdictional certainty" contemplated by *Markman*?

2) Whether disputed terms in a patent claim should be construed by looking first and principally to the "intrinsic evidence" (*i.e.*, the patent's claim language, specification,

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[3] *See Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1356 (Fed. Cir. 2004) (dissent by Newman, J.)

[4] David J.F. Gross, et al., *You Must be Mistaken: Federal Circuit 'Corrections' of District Court Claim Constructions (2002-03)*, 766 PLI/Pat 47, 53 (2003) (error rate of 74% based on review of published claim construction decisions from approximately September 2002 through June 2003).

QUESTIONS PRESENTED – Continued

and prosecution history),[5] or by looking first and principally to extrinsic dictionary definitions to determine the term's "ordinary meaning," and then consulting the intrinsic evidence merely to determine if it contains a "manifest exclusion or restriction" of that "ordinary meaning"?[6]

3) Whether a patent claim should be broadly construed based on a dictionary-defined "ordinary meaning" to cover a device that was (a) not mentioned anywhere in the patent's specification, (b) not invented by the patent applicants, and (c) unknown in the art at the time that the patent was filed?[7]

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[5] *See, e.g., Markman*, 52 F.3d at 978-81.

[6] *See, e.g., Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002).

[7] *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004).

PARTIES TO THE PROCEEDINGS

Petitioner

Medrad, Inc.

Respondents

Liebel-Flarsheim Company and Mallinckrodt, Inc.

DISCLOSURE STATEMENT

Petitioner Medrad, Inc. is a wholly-owed subsidiary of Schering Berlin, Inc. Schering Berlin, Inc. is a wholly-owned subsidiary of Schering Aktiengesellschaft. There is no public company that holds more than 10 percent of Schering Aktiengesellschaft's stock.

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Manual of Patent Examining Procedure § 2163 (8th ed. August 2001, revised May 2004) 24

OTHER PUBLICATIONS

Gretchen Ann Bender, *Uncertainty and Unpredictability in Patent Litigation: The Time Is Ripe for a Consistent Claim Construction Methodology*, 8 J. Intell. Prop. Law 175 (2001) 23

David J.F. Gross, et al., *You Must be Mistaken: Federal Circuit 'Corrections' of District Court Claim Constructions (2002-03)*, 766 PLI/Pat 47 (2003) ii

Ben Hattenbach, *Chickens, Eggs, and Other Impediments to Escalating Reliance on Dictionaries in Patent Claim Construction*, 85 J. Pat. & Trademark Off. Soc. 181 (2003) 23

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Anthony R. Zeuli and Rachel Clark Hughey, *Avoiding Claim Construction Errors: Determining the Ordinary and Customary Meaning Before Reading the Written Description*, The Federal Lawyer, June 2004 28

PETITION

Petitioner Medrad, Inc. (hereinafter "Medrad") respectfully requests that a writ of certiorari issue to review the April 2, 2004 judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

This petition is from the Federal Circuit's published opinion in *Liebel-Flarsheim Co. v. Medrad, Inc.*, Nos. 03-1082, 03-1165, 358 F.3d 898 (Fed. Cir. 2004), issued on February 11, 2004. (App. 1-34). That decision reversed an unpublished judgment of the United States District Court for the Southern District of Ohio, dated October 30, 2002. (App. 35-36). The Federal Circuit, after calling for a response, denied Medrad's combined petition for panel rehearing and rehearing *en banc* on April 2, 2004. (App. 131-132).

A copy of the Federal Circuit's opinion is included in the Appendix at App. 1. A copy of the district court's judgment is included at App. 35. Copies of the district court's October 18, 2001, and February 19, 2002 rulings, which formed the basis for its judgment, are included at App. 37 and App. 105, respectively. A copy of the denial of the combined petition for panel rehearing and rehearing *en banc* is included at App. 131.

I.

JURISDICTION

The district court exercised jurisdiction over this matter pursuant to 28 U.S.C. § 1338(a). The district court

entered a final judgment on October 30, 2002, which was appealed by respondents to the United States Court of Appeals for the Federal Circuit pursuant to 28 U.S.C. § 1291 and 28 U.S.C. § 1295(a)(1). The Federal Circuit rendered its decision on February 11, 2004, and Medrad timely filed its combined petition for panel rehearing and rehearing *en banc* on February 25, 2004. On March 10, 2004, the Federal Circuit called for a response to that combined petition. On April 2, 2004 the Federal Circuit denied the combined petition. Medrad timely filed this Petition for Writ of Certiorari within 90 days of that denial. This Court has jurisdiction under 28 U.S.C. § 1254(1).

II.

STATUTORY PROVISIONS INVOLVED

Article I, Section 8, Clause 8 of the Constitution:

> Congress shall have the power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Respective Writings and Discoveries.

35 U.S.C. § 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 112 ¶¶ 1, 2:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear,

concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

III.

STATEMENT OF THE CASE

In this case, reliance on extrinsic dictionary definitions as a basis for patent claim construction passes the point of "absurdity." For the first time when applying a so-called "ordinary meaning" approach, a panel of the Federal Circuit has extended a patent claim beyond what the inventor actually invented and disclosed to a device that was admittedly unknown at the time the patent was filed. The Court embraced this result simply because the inventor did not "manifestly disclaim" this device anywhere in the patent's specification – an impossibility given that such a device was unknown at the time the patent was filed. Under this rationale, the scope of patent claims is no longer determined by what the inventor publicly disclosed as his or her actual invention, but instead depends on the broadest possible construction that a court can divine from an extrinsic dictionary long after the patent was filed.

This action was brought by the Respondent Liebel-Flarsheim Company (hereinafter "L-F"), in the United States District Court for the Southern District of Ohio in 1998, for infringement of U.S. Patent Nos. 5,456,669 ("the

'669 patent") (Pat. 1-23); 5,658,261 ("the '261 patent") (Pat. 24-46); 5,662,612 ("the '612 patent") (Pat. 47-68); and 5,928,197 ("the '197 patent") (Pat. 69-92). All four patents involve a medical device known as a power injector and the syringes used with it. Power injectors push contrast fluid from the syringe into a patient's bloodstream at a high pressure.

In the first two patents (the '669 and '261 patents), L-F only disclosed and described an injector and a syringe that used a "pressure jacket." (App. 52-55). In particular, L-F disclosed in the specifications of these patents that:

> According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is provided in the front end of the pressure jacket.

'669 Patent, col. 2, line 64 to col. 3, line 1 (Pat. 13-14); '261 Patent, col. 2, lines 61-65 (Pat. 36).

Medrad's power injectors and syringes, on the other hand, do not need or use a pressure jacket. (App. 4). Medrad was, in fact, the first to invent, and the first to file a patent that explicitly disclosed, pressure jacketless injectors and syringes. (App. 39). L-F nevertheless argued that because certain of its patent claims included the words "opening" or "syringe receiving opening," rather than the words "pressure jacket," the language of the claims was broad enough to include a jacketless injector. (App. 49-50). L-F maintained that the claims should read that way even though: (1) a jacketless injector did not exist in the prior art at the time its patent was filed (App. 38, 39); (2) a jacketless injector was not disclosed anywhere in

the specifications of the '669 and '261 patents (App. 52-53, 57), each of which referenced a pressure jacket over 100 times (Pat. 1-19, 23-42); (3) the specifications of the '669 and '261 patents defined the "opening" as being "in the front end of the pressure jacket" (App. 3-4, 52-55, 59); (4) all of the claims of the original patent application required and explicitly recited a "pressure jacket" (App. 58); and (5) at one point during the prosecution of the original patent application,[8] L-F specifically added the words "pressure jacket" back into every claim after attempting to remove them to "clarify the inventive concepts claimed."

The second two patents (the '612 and '197 patents) involved a similar dispute concerning whether the term "related to" should be construed in accord with its full dictionary definition or should be construed according to how it was used in the patents' specifications. (App. 118-119).

A. By Placing Initial And Primary Reliance On The Entire Intrinsic Record When Construing The Disputed Claim Terms, The District Court Found No Infringement

Based on a review of the intrinsic evidence (the claim language, specification, and prosecution history of the patents), the district court construed the disputed claim terms "opening" and "syringe receiving opening" as used in the '669 and '261 patents to be limited to the open front

[8] The original "patent application" mentioned here is the parent application to, and has the same specification as, the '669 and '261 patents. (App. 39 n.2). Statements made or actions taken in the prosecution of this original parent application limit the coverage in the later filed '669 and '261 patents.

end of a pressure jacket. (App. 62-63). In so doing, the district court rejected the dictionary definition of "opening," e.g., "APERTURE," because it was "ambiguous with respect to the requirement of a pressure jacket." (App. 51-52). Citing *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-83 (Fed. Cir. 2000), and *Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1382 (Fed. Cir. 1999), the district court opined that "the asserted claims do not cover a jacketless injector, even though the asserted claims might be considered broad enough to disclose a jacketless injector when read without reference to the specification" because the "specification makes clear that the injector includes a pressure jacket." (App. 55).

The district court similarly rejected a broad dictionary definition of "related to" as used in the '612 and '197 patents based on its review of the intrinsic evidence, holding that a narrower construction of the term was "readily apparent from the language of the asserted claims themselves." (App. 120).

B. By Placing Initial And Exclusive Reliance On Extrinsic Dictionary Definitions When Construing The Disputed Claims, The Federal Circuit Rejected The District Court's Claim Construction

The Federal Circuit reversed the district court on all four patents. (App. 2). The Federal Circuit relied on an extrinsic dictionary definition to hold that "[i]n common usage, an opening is simply an aperture." (App. 13).[9]

[9] Although the Federal Circuit did not explicitly state where it found this definition of "opening," it is evident that this definition is

(Continued on following page)

Citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002), and *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002), the Federal Circuit noted that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" (App. 14) (citing *Teleflex*, 299 F.3d at 1327). Thus, although it was undisputed that a jacketless injector was unknown in the art and was not disclosed in L-F's patent specification (App. 39, 52 n.10, 56), because L-F had not manifestly disclaimed a jacketless injector, the patent claims and the term "opening" were held to cover a jacketless injector. (App. 8, 18-19, 26).

In arriving at this more expansive construction, the panel explicitly rejected several published precedents relied on by Medrad (App. 14-18), including *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001); *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999); *Biogen, Inc. v. Berlex Labs, Inc.*, 318 F.3d 1132, 1139-40 (Fed. Cir. 2003); *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-83 (Fed. Cir. 2000); *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000); *Modine Manuf. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550-51 (Fed. Cir. 1996); and *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1301-02 (Fed. Cir. 1999), all of which provide that the language of the specification should be considered and applied in determining the meaning of the claim without

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taken from the dictionary definition cited by the district court. *Compare* App. 51 *to* App. 13.

regard to extrinsic evidence, such as a dictionary definition. (App. 14-18).

In construing the phrase "physical indicia related to" in the second dispute, the Federal Circuit took the same approach. It rejected the district court's claim construction analysis based on the intrinsic record, and instead gave the broadest possible dictionary meaning to the disputed claim terms. (App. 33).

IV.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's jurisprudence on claim construction has been in a chaotic state for several years. How else could one explain the 74% rate of reversal of district court claim construction decisions in 2002-2003? In the current circumstances, lower courts spend countless hours adjudicating patent cases only to have their decisions overturned. Litigants spend hundreds of thousands of dollars and years of effort needlessly. Patent owners and aspiring patentees alike are prevented from realizing the true value of their inventive efforts, as they are unsure about what any particular patent covers.

Although the Federal Circuit attempted to clarify the process of claim construction in 1995 with its *en banc* decision in *Markman*, 52 F.3d 967, divergent schools of thought have evolved among the members of that Court in the ensuing years. In essence, the Federal Circuit is divided between intrinsic, *Markman*-based claim construction and extrinsic, dictionary-based claim construction. Further, these disparate approaches are applied in an unpredictable manner so that inventors, patent owners,

businesses, litigants, members of the patent bar, and even the district courts, cannot possibly know how claims will be construed until after a Federal Circuit decision has been rendered. *See* Gross, *supra* footnote 4, at 113 ("A cynic may respond by suggesting that district courts should do nothing more than figure out ways to move cases to the Federal Circuit early so that the Federal Circuit can determine the 'correct' interpretation before the litigants and courts spend too much time and resources on the case.").

The state of the law governing claim construction has deteriorated so badly that not only commentators, but also members of the Federal Circuit, have noted the lack of reliable results in patent matters. Only two months ago, comments by Judge Newman, in *Housey Pharmaceuticals v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1356 (Fed. Cir. 2004), highlighted the problem: "My colleagues' approach to construction is based on confusing recent pronouncements of panels of this Court, contravening earlier statements of precedent, thus adding to the confusion."

With billions of dollars spent annually on research and development, and with hundreds of millions dollars at stake in patent infringement cases annually, this chaotic situation must end. This Court explained why in its opinion in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002): "A patent holder should know what he owns, and the public should know what he does not." Neither patent holders, nor the public, are in that position now. It is instead apparent that the "intrajurisdictional certainty" hoped for in *Markman* has not been realized, and that the Federal Circuit has been unable or unwilling to resolve the confusion in a timely fashion. It therefore is appropriate and necessary for this

Court to end the conflict and bring uniformity and predictability to claim construction in patent cases.

A. The *Markman* Decisions Were Intended To Bring Uniformity And Predictability To Patent Claim Construction

In *Markman*, the *en banc* Federal Circuit addressed two critical issues on which federal courts had divided: (1) whether patent claims should be construed by a judge or a jury; and (2) what evidence principally should be considered in construing patent claims.

On the first issue, the Federal Circuit held that claim construction is a legal issue to be decided by the court. *Markman*, 52 F.3d at 979. On the second, "[b]ecause patents are fully integrated written instruments," the Federal Circuit placed dispositive emphasis on the so-called "intrinsic evidence" in construing a claim: the claim language, specification, and prosecution history. *See id.* at 978-79 ("[c]laims must be read in view of the specification, of which they are a part."). Although a court may consult "extrinsic evidence," including dictionaries, such "evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Id.* at 981. Thus, under the *en banc* opinion in *Markman*, intrinsic evidence "is of primary significance in understanding the claims," and extrinsic evidence, such as a dictionary, is considered only when the intrinsic evidence does not provide an answer on the meaning to be given disputed claim terms. *See id.* at 978-80.

In affirming the Federal Circuit in *Markman*, this Court agreed that "the construction of a patent, including terms of art within its claims, is exclusively within the

province of the court." *Markman*, 517 U.S. at 372. By giving construction disputes to the courts and not juries, this Court expressed its desire to promote greater "intra-jurisdictional certainty" with regard to claim construction decisions. *Id.* at 391. This Court also specifically endorsed a construction approach utilizing the entire "intrinsic record," emphasizing that standard rules of construction required that a patent's terms should "be defined only in a way that comports with the instrument as a whole." *Id.* at 389.

B. In Contravention Of The *Markman* Decisions, There Now Is A Confusing And Unacceptable Split Within The Federal Circuit Concerning The Proper Approach To The Construction Of Patent Claims

Although the respective *Markman* decisions plainly were intended to bring consistency to patent claim construction, they unfortunately have not achieved their central purpose. The intervening years have not established the hoped for "intrajurisdictional certainty." *Markman*, 517 U.S. at 391. On the contrary, the Federal Circuit now employs two divergent approaches to patent claim construction: one placing primary reliance on the intrinsic record as endorsed in *Markman*; and another more recent one placing primary reliance on non-technical dictionary definitions at the expense of the intrinsic record.

The differing resolutions by the district court and Federal Circuit in this case bring this intracircuit conflict sharply into focus. Simply put, and as illustrated here, the competing approaches to patent claim construction are not reconcilable – the selection of one or the other is outcome determinative and leads to opposite results. What remains

is an unstable legal environment in which the public, the district courts, and even the Federal Circuit's own judges, can no longer determine the controlling legal rules.

Perhaps not surprisingly, the deleterious effect of these published conflicting views falls most heavily on the district courts. Those courts – on the front lines of the claim construction disputes – do not know which approach to follow, and they are at risk of reversal depending on which one they choose. The result is costly judicial inefficiency that relegates patent claim construction to the proverbial "crap shoot." Incredibly, the Federal Circuit's reversal rate for claim construction decisions recently reached an indefensible 74%. *See* Gross, *supra* footnote 4, at 53.

In this case, the Federal Circuit also has taken the utilization of dictionary definitions to an illogical extreme. Here, the Federal Circuit unilaterally defined a claim term to cover a particular embodiment that admittedly was *not* disclosed in the patent specification (App. 56) and concededly was *unknown* in the art at the time the patent was filed. (App. 39). The inventors therefore got credit for something they did not invent or intend to patent. This is problematic because the entire patent system – as established by the Constitution and The Patent Act and as affirmed by the jurisprudence of this Court and other federal courts – is designed to protect only what inventors actually discovered and expressly disclosed. *See* U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 101; 35 U.S.C. § 112 ¶ 1, 2; *Markman*, 517 U.S. at 373. The Federal Circuit's opinion below is thus one of those "absurd results" identified by Judge Newman in her dissent in *Housey Pharmaceuticals*, 366 F.3d at 1356, where she outlines the flaws

inherent in placing primary reliance on dictionary definitions at the expense of the full intrinsic record.

With hundreds of millions of dollars at stake in patent infringement suits nationwide, our legal system cannot tolerate this kind of uncertainty or absurdity. As Judge Newman also succinctly stated in *Housey Pharmaceuticals*: "It is time to restore the law of claim construction to a more apt wisdom and more usable simplicity." *Id.* at 1356. The ability to assess the scope of claims using a uniform approach on a consistent basis to achieve predictable results is fundamental to the patent system and of great importance to the lower courts, the patent bar, and the commercial world. Indeed, this Court recently underscored the paramount importance of these concerns in its opinion in *Festo Corp.*, 535 U.S. at 730-31:

> The [patent] monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not.

A critical body of federal commercial law is now so confused that a district court's chances of being affirmed on appeal are less than its chances of winning a coin toss. Only this Court, in the exercise of its supervisory powers, can remedy this clear departure from the accepted and usual course of judicial appellate review. *See* Sup. Ct. R. 10(a) ("Considerations Governing Review on Certiorari").

C. The Federal Circuit's Competing Approaches To The Construction Of Patent Claims Are Outcome Determinative But Not Reconcilable

1. The Patent Claim Construction Decisions That Follow A *Markman*-Based Approach Place Initial And Primary Reliance On The Entire Intrinsic Record Before Considering Extrinsic Evidence

The Federal Circuit decisions following *Markman* make intrinsic evidence the linchpin of the construction analysis, and refuse to allow extrinsic evidence – and particularly a dictionary definition – to trump the meaning derived from the intrinsic record.

For example, in *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473 (Fed. Cir. 1998), the Federal Circuit emphasized that "the court starts the [claim construction] process" by reviewing the same sources as would a person of ordinary skill in the field of invention, "viz., the patent specification and the prosecution history." *Id.* at 1477; *see also Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004). The patent specification and prosecution history "have legal as well as technological content, for they show not only the framework of the invention as viewed by the inventor, but also the issues of patentability as viewed by the patent examiner." *Multiform Desiccants*, 133 F.3d at 1477.

Under this *Markman*-based approach, extrinsic evidence (like a dictionary or other independent source) may be consulted only *after* first considering the import of the patent's specification: "Courts must exercise caution lest dictionary definitions . . . be converted into technical terms of art having legal, not linguistic, significance. The

best source for understanding a technical term is the specification from which it arose . . . When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Id.* at 1478.

Further, consistent with the reasoning in *Markman*, a dictionary is relied on in claim construction only to the extent that "the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582, 1584 & n.6 (noting that the specification "[u]sually . . . is dispositive" in claim construction and "is the single best guide to the meaning of a disputed term"); *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 705-06 (Fed Cir. 1997) ("When construing a claim, a court should look first to the intrinsic evidence. . . . When the intrinsic evidence is unambiguous, it is improper for the court to rely on extrinsic evidence."); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("[A] common meaning, such as one expressed in a relevant dictionary, that flies in the face of the patent disclosure is undeserving of fealty."); *Toro Co.*, 199 F.3d at 1299-1302 (rejecting dictionary definitions and emphasizing that claim terms must be construed "in the context in which they were used by the inventor, considered by the examiner, and understood in the field of the invention"); *Vanderlande Indus.*, 366 F.3d at 1322 (rejecting dictionary definition as being "entirely eclipsed by the . . . patent's written description").

In fact, in keeping with the *Markman*-based approach, where a particular claim term has no special meaning in the relevant industry (independent of the specification), "general-usage dictionaries are rendered irrelevant with

respect to that term." *Vanderlande Indus.*, 366 F.3d at 1321. Thus, "[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." *Vitronics*, 90 F.3d at 1583.

2. The Patent Claim Construction Decisions That Follow The "Ordinary Meaning" Approach Place Initial And Primary Reliance On Extrinsic Evidence At The Expense Of The Intrinsic Record

Rather than placing primary reliance on the intrinsic record, a divergent line of Federal Circuit decisions places primary and dispositive emphasis on the "ordinary meaning" of claim terms as ascertained by reference to extrinsic dictionary definitions. *See, e.g.*, *Liebel-Flarsheim*, 358 F.3d at 905 (App. 11-13); *Teleflex, Inc.*, 299 F.3d at 1327; *Texas Digital*, 308 F.3d at 1202-04.

These cases hold that court-selected dictionary definitions disclose a claim term's "ordinary meaning," and that there is a "heavy presumption" that such a dictionary-defined "ordinary meaning" is correct. Under this "ordinary meaning" approach, the patent's specification is relegated to the back seat, and is relevant only insofar as it demonstrates "a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *See Liebel-Flarsheim*, 358 F.3d at 906 (*citing Teleflex*, 299 F.3d at 1327) (App. 13-15).

3. The *Markman*-Based And The "Ordinary Meaning" Approaches To Patent Claim Construction Are Irreconcilable And Lead To Inconsistent Results

The *Markman*-based approach and the "ordinary meaning" approach – both reflected in the Federal Circuit's published case law – conflict with each other in three fundamental and irreconcilable ways.

First and foremost, the "ordinary meaning" approach gives dispositive weight to court-selected, extrinsic dictionary definitions in the claim construction analysis. Non-technical dictionaries are viewed as the "most meaningful sources of information to aid judges in better understanding both the technology and terminology used by those skilled in the art to describe the technology." *Texas Digital*, 308 F.3d at 1203. In contrast, cases that use the *Markman*-based analysis focus on the specification and relegate dictionary definitions to the proverbial back seat. *See, e.g.*, *Vitronics Corp.*, 90 F.3d at 1582 (the specification "[u]sually . . . is dispositive" in claim construction and "is the single best guide to the meaning of a disputed term"); *Vanderlande Indus.*, 366 F.3d at 1322 (ordinary dictionary definition of "glide surface" is "entirely eclipsed" by the patent's written description).

Second, and equally important, under the "ordinary meaning" approach, the meaning of the claim term is determined *first* by reference to a non-technical dictionary. *See, e.g., Texas Digital*, 308 F.3d at 1205. The remaining "intrinsic evidence," such as the specification and written description, is considered only if the court-selected dictionary meaning fails to resolve the issue. *Id.* at 1204; *see, e.g., Housey Pharmaceuticals*, 366 F.3d at 1352; *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*, 309

F.3d 1373, 1382 (Fed. Cir. 2002). Under *Markman*, in contrast, *all* of the intrinsic evidence is considered *first*, and extrinsic evidence is considered only if the claim term's meaning remains ambiguous in light of the intrinsic evidence. *See Multiform Desiccants*, 133 F.3d at 1477-78.

Third, and just as fundamental, by placing paramount reliance on court-selected dictionary definitions, the "ordinary meaning" approach disregards what the inventors actually invented, as disclosed by their own patent application, and what the Patent Office examined in granting the patent. As the Federal Circuit stated here: "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim*, 358 F.3d at 906 (App. 13-15).

However, as Judge Newman has explained, this express disregard for the written description also conflicts with *Markman*: "Precedent is exactly contrary: a claim is 'inimical' to any broader construction than the invention set forth in the specification, and reliance on dictionaries, even technical dictionaries, without due consideration of the context of the invention may lead to 'absurd results.'" *Housey Pharmaceuticals*, 366 F.3d at 1356.

Judge Michel, in his very recent concurrence in *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 896-98 (Fed. Cir. 2004), also noted the dispositive differences between the "ordinary meaning" and the *Markman*-based approaches and captured the essence of the problem the conflict engenders:

> I am concerned then that the use of these "shorthand" expressions about ordinary meaning obscures the correct analysis, tempting panels to look for an "ordinary meaning" divorced from the proper perspective – the artisan's – and the preferred, proper sources of interpretation – the disclosure, technical dictionaries, prior art patents, and expert testimony. The ultimate result of this trend is claim constructions providing the broadest possible scope to claim terms, absent express limiting language in the claim, specification or prosecution history, but regardless of what the inventors actually invented.

Id. at 898.

These dichotomies, aptly described by the Federal Circuit's own judges and highlighted here, are by no means trivial or just a matter of semantics. The construction approach a court selects can be dispositive of claim construction. Depending on the composition of panels and the approach the judges favor, results can vary as well. *See* R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 Univ. of Pennsylvania Law Review 1105, 1112 (2004).

4. This Case Starkly Illustrates The Dispositive Effect Of The Choice Of One Claim Construction Approach Or The Other

This case provides an unusually stark illustration of how the selection of one claim construction approach or the other can control the outcome of a claim construction dispute. There is no question here, for example, that L-F's

patented medical device requires a pressure jacket and that the specification and prosecution history reveal that the syringe receiving "opening" is in the front of the pressure jacket. Only by ignoring the specification and prosecution history, in favor of a much broader and non-technical dictionary definition, can L-F's patent claim be read to cover Medrad's jacketless injector. The same goes for "physical indicia related to." When that phrase is considered in light of what L-F actually invented – as revealed from the specifications and prosecution history – it has no colorable relevance to Medrad's device.

The irreconcilable nature of these conflicting approaches is further illustrated by *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1346-51 (Fed. Cir. 2004) – a case published just eight days before this one with remarkably similar facts but a totally different outcome.[10] In *Microsoft*, "transmitting" was limited to transmission over a telephone line by the district court just like "opening" was limited to the opening at the front of the pressure jacket by the district court in the present case. In *Microsoft*, transmission over a telephone line was mentioned two dozen times in the specification, the stated "invention" included telephone lines, and the specification did not mention transmission that was not over a telephone line. Similarly, in this case, pressure jacket is mentioned over 135 times in the specification, the "invention" included a pressure jacket, and the specification did not mention an

[10] Medrad understands that Multi-Tech Systems is also filing a Petition for Writ of Certiorari from this decision by the Federal Circuit during the week of June 28, 2004. Presumably, its petition will also address the Federal Circuit's divergent claim construction approaches.

injector that did not include a pressure jacket. (App. 52-55, 57; Pat. 1-19, 23-42).

In *Microsoft*, however, unlike the present case, the Federal Circuit affirmed summary judgment of non-infringement based on the district court's narrow construction of the claim term at issue ("transmitting"). The Federal Circuit did not reference the "ordinary meaning" and "manifest exclusion" analysis it used in this case, but rather relied on the *Markman*-based approach wherein "the claims must be interpreted in light of the specification." *Microsoft*, 357 F.3d at 1347.

Had the *Markman*-based approach employed in *Microsoft* been applied in the present case, the district court's claim construction would have been affirmed. And, had the "ordinary meaning" approach applied by the Federal Circuit in this case been applied in *Microsoft*, the outcome would have been different there as well.

5. The Intolerable Uncertainty Created By The Federal Circuit's Conflicting And Competing Patent Claim Construction Approaches Should Be Rectified Now By This Court

a. The Federal Circuit's Competing Claim Construction Opinions Provide Inadequate Guidance And Exacerbate The Conflict

As Judge Dyk acknowledged when examining this intracircuit conflict three years ago: "our decisions provide inadequate guidance as to when it is appropriate to look to the specification. . . . Until we provide better guidance, I fear that the lower courts and litigants will remain

confused." *SciMed Life Sys., Inc.*, 242 F.3d at 1347 (concurring opinion); *see also VLT Corp. v. Lambda Elect., Inc.*, 238 F. Supp. 2d 347, 350 (D. Mass. 2003) (describing the Federal Circuit's precedents as "a bit schizophrenic on the relationship between the claim language and the specification of a patent"); *BorgWarner, Inc. v. New Venture Gear, Inc.*, 237 F. Supp. 2d 919, 928 (N.D. Ill. 2002) (discussing the "tension" in the Federal Circuit's precedent concerning the role of the specification in claim construction).

Despite Judge Dyk's plea, the confusion has persisted and gotten worse, not better. For example, just three months ago, Judge Dyk dissented from a claim construction decision because "[t]he majority decision effectively limits the claims to the preferred embodiment, contrary to our recent decision in *Liebel-Flarsheim*, 358 F.3d 898, and numerous other decisions of this Court." *Phillips v. AWH Corp.*, 363 F.3d 1207, 1216 (Fed. Cir. 2004). Just two months ago, by comparison, Judge Newman dissented from a claim construction decision that employed the "ordinary meaning analysis" because: "My colleagues' approach to construction is based on confusing recent pronouncements of panels of this Court, contravening earlier statements of precedent, thus adding to the confusion." *Housey Pharmaceuticals*, 366 F.3d at 1356.

Apart from the Federal Circuit's own judges, the persistence of this intracircuit inconsistency, as well as the fundamental problems it engenders for claim construction, have been highlighted by commentators as well:

> The Federal Circuit's lack of a consistent claim construction methodology becomes most apparent when trying to determine when extrinsic evidence, particularly dictionaries and treatises,

> may be considered. . . . In many cases, the Federal Circuit determines the plain and ordinary meaning of the claim terms by relying on extrinsic evidence, such as dictionaries and even expert testimony. In other cases, the court ignores extrinsic evidence about the ordinary meaning of claim terms. In sum, not only are the claim construction canons ideologically flawed (and impossible to apply), but also the Federal Circuit does not approach claim construction consistently. Under the circumstances, uncertainty and unpredictability in patent cases will undoubtedly continue.

Gretchen Ann Bender, *Uncertainty and Unpredictability in Patent Litigation: The Time Is Ripe for a Consistent Claim Construction Methodology*, 8 J. Intell. Prop. Law 175, 217 (2001).[11]

b. The Persistent Conflict In Claim Construction Approaches Erodes The Role Of The PTO

This persistent conflict in approaches adversely impacts the role of the Patent and Trademark Office

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[11] *See also* Ben Hattenbach, *Chickens, Eggs, and Other Impediments to Escalating Reliance on Dictionaries in Patent Claim Construction*, 85 J. Pat. & Trademark Off. Soc. 181, 182, 190 (2003) (noting that recent Federal Circuit cases on use of dictionary definitions "deviated from established principles of construction" and that earlier cases "struck a sensible balance between dictionaries and specifications"); Russell B. Hill and Frank P. Cote, *Ending the Federal Circuit Crapshoot: Emphasizing Plain Meaning in Patent Claim Interpretation*, 42 IDEA: The Journal of Law and Technology 1, 1 (2002) ("The tension between these camps [regarding the role of plain meaning in patent claim interpretation], which is driven by competing canons of claim construction, results in uncertainty for litigants and wasted judicial resources.").

("PTO") as well. By giving judge-selected dictionary definitions priority over the intrinsic specification, the Federal Circuit's "ordinary meaning" approach invites courts to construe claim terms more broadly than the limits directed in the patent's specification. But the PTO, as part of its threshold oversight function, is directed to reject any claims that it finds are unsupported by the specification. *See* Manual of Patent Examining Procedure § 2163 (8th ed. August 2001, revised May 2004). Thus, from the Federal Circuit's "ordinary meaning" perspective, the specification has little, if any, significance whatsoever, while from a regulatory perspective it is supposed to be dispositive. This anomalous result further compromises the efficacy of the PTO.[12]

c. The Persistent Conflict In Claim Construction Approaches Erodes The Important Notice Function Of The Patent System

The Federal Circuit's persistent conflict in claim construction approaches erodes the important notice

[12] This anomaly is reason alone to reject the "ordinary meaning" approach. *See, e.g., Festo Corp.*, 535 U.S. at 738 (adopting legal rule that is "respectful of the real practice before the PTO"); *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997) (declining to adopt legal rule where "the PTO may have relied upon a [different] rule . . . when deciding whether to [issue a patent] in the first place"); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18-19 (1966) (decrying "a notorious difference between the standards applied by the Patent Office and by the courts," and adopting legal rule that would "bring about a closer concurrence between administrative and judicial precedent"). The specification, which "show[s] not only the framework of the invention as viewed by the inventor, but also the issues of patentability as viewed by the patent examiner," *Multiform Desiccants*, 133 F.3d at 1477, provides much surer guidance to the meaning of a disputed claim term than an extrinsic dictionary definition.

function supplied by the public record or "intrinsic evidence." *See, e.g., Markman*, 517 U.S. at 390 ("The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.") (citation omitted). As the Federal Circuit has stated, "competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention." *Vitronics*, 90 F.3d at 1583.[13]

Nevertheless, the divergent claim construction approaches directly undermine this public notice function in two critical ways: first, by making it impossible for district courts, competitors, and the public to ascertain how a claim will be construed; and second, by diminishing the extent to which anyone can rely on the public record to determine what actually has been claimed. For these reasons, a competitor never really can be sure which approach will be used and what role the public record will subsequently play in claim construction.

In such an environment, there is little left of the public notice function that is at the heart of the patent system. While the intrinsic specification is part of "the public record of the patentee's claim" examined by the

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[13] *See also Bates v. Coe*, 98 U.S. 31, 39 (1878) ("Accurate description of the invention is required by the law, for several important purposes: 1. That the government may know what is granted, and what will become public property when the term of the monopoly expires. 2. That licensed persons desiring to practise [sic] the invention may know during the term how to make, construct, and use the invention. 3. That other inventors may know what part of the field of invention is unoccupied.").

PTO, *Vitronics*, 90 F.3d at 1583, judge-selected dictionary definitions are not. Allowing an inventor to broaden a claim's scope by a judge's hindsight reliance on a dictionary definition thus renders "meaningless" the public's right to rely on the intrinsic record. *Id.*

d. The Persistent Conflict In Claim Construction Approaches Erodes The Patent System Itself

In the end, the Federal Circuit's persistent conflict in claim construction approaches erodes the patent system itself. The U.S. Constitution and the Patent Act set up the patent system to secure to "Inventors the exclusive right to their . . . Discoveries." U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 101. The Patent Act further requires that the inventor provide a "written description of the invention" in "full, clear, concise, and exact terms." 35 U.S.C. § 112, ¶ 1. Thus, as this Court has noted:

> It has long been understood that a patent must describe the exact scope of an invention and its manufacture to "secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them."

Markman, 517 U.S. at 373 (citations omitted) (additions and quote as in original).

As is starkly illustrated in this case, the choice of claim construction approach can greatly impact the scope and coverage of the claims. The persistent conflict in approaches thus erodes the patent system by making it impossible to "apprise the public of what is still open to them." *See id.*

Moreover, the "ordinary meaning" approach employed by the Federal Circuit also erodes the system by disregarding what the inventor actually invented and disclosed. As described by the *en banc* Federal Circuit, the patent system, in essence, works a "deal" between the inventor and the government:

> The inventor is required to make full disclosure of his invention to the Patent and Trademark Office (PTO) and to the public in his patent specification, which he is otherwise not obligated to do. In return, the law allows the government to confer a property right to exclude anybody else from making, using, or selling the invention covered by the claims for seventeen years, which it is not obligated to do.

Markman, 52 F.3d at 985. Yet, by disregarding what actually was disclosed by the inventor, the continued reliance on the "ordinary meaning" approach directly undermines the deal that is at the heart of the Patent System.

e. The Time Is Ripe For Laying The Conflict In Claim Construction Approaches To Rest

Given the uncertainty and absurdity inevitably engendered by the "ordinary meaning" approach, the *Markman*-based reliance on the entire intrinsic record should be preferred and restored to favor. But whatever approach is deemed most desirable, the present conflict in the legal standards applicable to patent claim construction should be immediately laid to rest. The district courts, affected competitors, litigants, the PTO, and ultimately the patent system, all are casualties of this divergence.

Uniformity and predictability from judicial decision making should be paramount goals in this context given the hundreds of millions of dollars at stake on patent infringement issues. Yet, the Federal Circuit's own decisions, when combined with its reversal rate, reveal how badly these goals are being compromised. In short:

> Trial judges are frustrated. Lawyers grapple with the uncertainty of the process. Clients loathe the expense.

Anthony R. Zeuli and Rachel Clark Hughey, *Avoiding Claim Construction Errors: Determining the Ordinary and Customary Meaning Before Reading the Written Description*, The Federal Lawyer, June 2004, at 29.

Seven years have passed since *Markman* and it is now apparent that the hoped-for intrajurisdictional certainty in claim construction will not be achieved without this Court's intervention. Only this Court can definitively set the law back on its proper course.

V.

CONCLUSION

Now is the time to provide clarification in the law governing patent claim construction and this case provides an excellent vehicle do to so. This Court should grant the petition for writ of certiorari, set the case for plenary review, and issue an opinion endorsing the *Markman*-based approach to patent claim construction.

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Respectfully submitted,

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358 F.3d 898

United States Court of Appeals,
Federal Circuit.

LIEBEL-FLARSHEIM COMPANY and
Mallinckrodt Inc., Plaintiffs-Appellants,
v.
MEDRAD, Inc., Defendant-Cross Appellant.

Nos. 03-1082, 03-1165.

Feb. 11, 2004.
Rehearing and Rehearing En Banc Denied April 2, 2004.

J. Robert Chambers, Wood, Herron & Evans, L.L.P., of Cincinnati, OH, argued for plaintiffs-appellants. With him on the brief was Theodore R. Remaklus.

James F. Davis, Howrey Simon Arnold & White, LLP, of Washington, DC, argued for defendant-cross appellant. On the brief for the defendant-cross appellant were Frederick H. Colen and Barry J. Coyne, Reed Smith LLP, of Pittsburgh, PA. Of counsel was Kirsten R. Rydstrom, Reed Smith LLP, of Pittsburgh, PA.

Before LOURIE, BRYSON, and DYK, Circuit Judges.

BRYSON, Circuit Judge.

Appellants Liebel-Flarsheim Company and Mallinckrodt Inc. (collectively, "Liebel") filed an action against appellee Medrad, Inc., in the United States District Court for the Southern District of Ohio, No. C-1-98-858, charging Medrad with infringement of four of Liebel's patents. The patents claim certain methods and devices for use in connection with powered fluid injectors, which can be used to inject fluids into patients during medical procedures. One of the patents, U.S. Patent No. 5,456,669 ("the '669

patent"), is drawn to methods of loading powered injectors from the front. A related patent, U.S. Patent No. 5,658,261 ("the '261 patent"), is drawn to front-loadable powered injectors and to disposable front-loadable syringes for use in such injectors. The other two patents, U.S. Patent Nos. 5,662,612 ("the '612 patent") and 5,928,197 ("the '197 patent"), which are also related, are drawn to injectors and syringes for use in powered injectors, and to devices and methods for controlling the plunger drives in such powered injectors.

On motions for summary judgment, the district court ruled that Medrad did not infringe any of the asserted claims of the four Liebel patents. The district court based its summary judgment ruling on its construction of the asserted claims. In the case of the first two patents, the court concluded that the asserted claims required the use of pressure jackets around the syringes used in the powered injectors. In the case of the latter two patents, the court concluded that the asserted claims required that the powered injector directly use an electrical signal generated by a detector to compute values for various physical properties of the syringes used in the injector. Because Medrad's accused injectors did not use pressure jackets and because the electrical signals in Medrad's devices were not directly used to compute any such values, the court granted summary judgment of noninfringement as to all of the claims set forth in Liebel's complaint. The court then dismissed the counterclaims, in which Medrad alleged that the asserted claims of the four patents were invalid. The court held that the counterclaims were moot in light of the court's noninfringement ruling. We reverse the grant of summary judgment and the dismissal of the counterclaims, and we remand for further proceedings.

I

Powered injectors are used in various medical applications, such as injecting contrast agents into the vascular systems of patients who undergo certain diagnostic imaging procedures. A powered injector ordinarily uses a motor drive that is attached to a syringe plunger. The drive pulls the plunger rearward to draw contrast agent into the syringe and then drives the plunger forward to inject contrast agent through a tube and into the patient. The contrast agent is usually injected into the patient under high pressure.

A

Liebel asserted that Medrad's powered injectors infringed seven claims of the '669 patent and twenty claims of the '261 patent. The '669 and '261 patents derive from a 1991 application, Ser. No. 712,110 ("the '110 application"). Prior to the filing of the '110 application, the injectors sold by both Liebel and Medrad required that the syringes be breech loaded, i.e., loaded through the rear of the injectors. Breech loading has disadvantages, including inefficiency in the loading process and the risk of spillage and contamination that can result from disconnecting the syringe from the tube through which contrast agent is delivered to the patient. The '110 application and the patents that eventually issued from it were directed to front loading, rather than breech loading, the powered injectors.

The specifications of the '669 and '261 patents are essentially identical. Each of the embodiments of the injector described in the two patents includes a pressure jacket into which the syringe is inserted. The pressure

jacket surrounds the syringe and prevents it from breaking under the internal pressure generated when the contrast agent is injected into the patient. Based largely on the fact that the '669 and '261 patents do not contain any description of an injector that lacks a pressure jacket, the district court construed all of the asserted claims from those two patents to require a pressure jacket, even though none of the asserted claims expressly refers to a pressure jacket. The district court concluded that "the specification makes clear that the injector includes a pressure jacket." Based on that observation, the court ruled that "the asserted claims do not cover a jacketless injector, even though the asserted claims might be considered broad enough to disclose a jacketless injector when read without reference to the specification."

The parties agree that Medrad's accused devices do not use pressure jackets. Because the district court construed the claims to require pressure jackets, the district court granted summary judgment of noninfringement as to the '669 and '261 patents. Liebel appeals the claim construction of the '669 and '261 patents and the summary judgment of noninfringement based on that construction.

B

Liebel also asserts that Medrad has infringed four claims of the '612 patent and eighteen claims of the '197 patent. The '612 and '197 patents, which are related and have a common specification, address the use of syringes, including prefilled syringes, in powered injectors. Different prefilled syringes contain different amounts of fluid. In order to accommodate syringes containing different amounts of fluid and to ensure that the right amount of

fluid is injected into the patient, the powered injectors must have a way of ensuring that the injector can detect critical features of the particular syringe that is being used.

The '612 and '197 patents solve that problem by providing that the syringes have "physical indicia related to" various syringe properties that enable the injector to calibrate the amount of fluid to be injected into the patient. Each of the asserted claims requires that the syringe possess "physical indicia" that can be detected by a detector and can provide information about the syringe properties of interest. Those properties include the capacity of the syringe or the amount of fluid in the syringe ('612 patent, claims 7 and 10; '197 patent, claims 7, 10, and 27); the distance of the plunger from the end of the syringe ('197 patent, claims 1 and 4); the distance to the end of the plunger's travel position ('197 patent, claims 13 and 16); and the range of travel of the ram, which attaches to the syringe plunger and moves the plunger in and out of the syringe ('197 patent, claims 19 and 22).[1] The claims further provide that the injector's control circuitry will control the plunger, based on the particular property detected, so as to inject the correct amount of fluid from the syringe.

The common specification of the '612 and '197 patents describes each syringe as including a plunger, which is

[1] The district court noted that claim 25 of the '197 patent does not refer to the detection of physical indicia "related to" particular syringe properties, but instead recites that the control circuit "obtain[s] an offset value from physical indicia detected on the syringe." Thus, the court concluded that claim 25 requires that the information detected from the physical indicia actually constitute the offset value.

grasped by a drive jaw. The drive jaw, which is connected to a motor and control circuitry, pushes the plunger into the syringe to inject the fluid into the patient. The specification teaches that prefilled syringes may include an extender that changes the position of the plunger relative to the drive jaw. If the length of the extender is not accounted for, the drive jaw may not be properly positioned, which would cause the injector to malfunction. The specification provides that a malfunction of that kind "is avoided by storing an offset value representative of the length of the extender . . . and applying this offset value to the computed drive jaw position." '612 patent, col. 3, ll. 59-61; '197 patent, col. 3, ll. 58-60.

Medrad argued in the district court that the term "physical indicia" should be limited to indicia representing the length of the extender. The specification, Medrad asserted, describes the use of "physical indicia" only to represent the length of the extender so that a proper "offset value" can be computed and the correct position of the drive jaw can be determined. Medrad also argued that the prosecution history supports its construction of the "physical indicia" limitation.

The district court disagreed with Medrad. The court ruled that the claim language was plainly broader than Medrad's proposed construction, as the claims expressly referred to syringe features other than the length of the extender. The court further held that the specification did not clearly disavow the use of physical indicia on the syringe that represented syringe properties other than the extender length. Moreover, the court determined that the prosecution history of the patents at issue supported the broader reading of the "physical indicia" limitation.

While the district court rejected Medrad's proposed claim construction, it did not construe the claim language as broadly as Liebel urged. Instead, the court ruled that the signal generated by the detector must be directly used in the computation of particular syringe properties. The court noted that "the claim language does not describe using the electrical signal generated by the detector to ascertain information from another source and then using this ascertained information to compute syringe properties." Accordingly, the court held that physical indicia are "related to" various syringe properties only "when the information detected from the physical indicia is/are the actual syringe properties or can be directly used in the computation of the various syringe properties without reference to some other source of information."

The evidence showed that the "physical indicia" on the syringes used in the Medrad injectors consisted of a series of indents, or the absence of indents, on the surface of the syringes. Electrical circuitry in the Medrad injectors would generate an electrical signal corresponding to the particular type of syringe being used. Based on a look-up table specifying the properties of the syringe that was detected, the Medrad injectors would determine the properties of the syringe in use.

Because the detection of physical indicia on Medrad's syringes generated electrical signals that indicated the type of syringe in use, rather than directly indicating the properties of the syringe, the district court concluded that the signal was only indirectly "related to" the syringe properties referred to in the asserted claims. An indirect relationship between the physical indicia and the syringe properties in question was not within the scope of the asserted claims as the district court construed them.

Accordingly, the court ruled that Medrad's accused injectors did not infringe any of the claims of the '612 or '197 patents.

II

Liebel's appeal with respect to the asserted claims of the '669 and '261 patents turns on whether the common specification of the two patents limits the scope of the asserted claims to injectors that include pressure jackets. We hold that it does not. The asserted claims do not expressly require pressure jackets, and the common specification does not state that a pressure jacket is a required component of the inventions. Moreover, even if the original disclosure supported Medrad's contention that the invention, as originally conceived, required the use of a pressure jacket, the prosecution history of the '669 and '261 patents makes clear that the patentee drafted the asserted claims specifically to cover injectors lacking pressure jackets. In light of the applicants' clearly stated intention to cover jacketless injectors, any question regarding the support or lack of support for the claims in the original disclosure bears on the issues of priority and validity, not on the issue of claim construction. Accordingly, for the reasons more fully set forth below, we conclude that the district court erred by construing the asserted claims to require pressure jackets.

A

Claim 10 of the '669 patent is representative of the asserted claims of the '669 and '261 patents. It provides as follows:

A method of loading a tubular replacement syringe into a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:

providing a power injector having:

a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim,

a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening; and providing a hollow tubular syringe that includes:

a cylindrical body having an axis, a generally circular rim, a rearward end and a closed forward end with a fluid discharge orifice therein, and

a plunger axially slidable in the body, the syringe body being structurally capable of withstanding, at least from the rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

then:

inserting into the opening, by generally rearward axial movement of the syringe, the rearward end of the body;

rotating the syringe in the opening a fraction of a turn to thereby lock the body around the rim to the injector around the periphery of the opening; and

engaging the plunger with the ram;

then:

> energizing the motor and thereby driving the ram forward along the line and parallel to the axis to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure from within the syringe and through the orifice at a programmed rate into the animal.

Neither claim 10 of the '669 patent nor any of the other asserted claims recites a pressure jacket. The district court, however, construed the claims to require pressure jackets by focusing on the "syringe receiving opening" limitation in claim 10 (and similar language used in the other asserted claims). After finding that limitation to be ambiguous with respect to the location of the opening, the court looked to the specification and concluded that, because the syringe-receiving opening in each of the embodiments of the invention was located at the front end of a pressure jacket, the "opening" referred to in each of the asserted claims had to be located at the front end of a pressure jacket. Medrad embraces the district court's claim construction analysis and makes the more general argument that because the "pressure-jacketed injector" is the only subject matter described in the specification, that subject matter constitutes the invention itself, not simply a preferred embodiment of a broader invention.

We have had many occasions to cite one or both of the twin axioms regarding the role of the specification in claim construction: On the one hand, claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). On the other hand, it is improper to read a limitation from the specification into the claims.

Arlington Indus., Inc. v. Bridgeport Fittings, Inc., 345 F.3d 1318, 1327 (Fed.Cir.2003); *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1343 (Fed.Cir.2001). Although parties frequently cite one or the other of these axioms to us as if the axiom were sufficient, standing alone, to resolve the claim construction issues we are called upon to decide, the axioms themselves seldom provide an answer, but instead merely frame the question to be resolved. We have recognized that "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed.Cir.1998); *accord Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1307 (Fed.Cir.2003). As we have explained, "an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims 'in view of the specification' without unnecessarily importing limitations from the specification into the claims." *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed.Cir.2003); *accord Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204-05 (Fed.Cir.2002). That problem can present particular difficulties in a case such as this one, in which the written description of the invention is narrow, but the claim language is sufficiently broad that it can be read to encompass features not described in the written description, either by general characterization or by example in any of the illustrative embodiments.

At the outset, we reject the district court's conclusion that the term "opening" should be defined as limited to an opening in a pressure jacket. The specification does not define "opening" restrictively, nor is there anything in the

specification that supports the district court's conclusion that the term is ambiguous. The asserted claims refer to the "syringe receiving opening," or simply the "opening," as having various characteristics, but none of the asserted claims state, explicitly or by necessary implication, that the opening must be formed in or in conjunction with a pressure jacket. Claim 10 of the '669 patent, for example, requires "a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening." The claim further provides that the rearward end of the syringe will be inserted into the opening and rotated in the opening to lock it in place. Thus, the "opening" must be located so that the ram reciprocates along a segment of a line projecting through the opening and so that the rear end of the syringe can be inserted into the opening and affixed to the injector at that point. But the claim language does not suggest that the "opening" must also be located at the front end of a pressure jacket.

Other asserted claims likewise refer to the location of the opening without referring to the location of the opening vis-a-vis a pressure jacket. For example, claim 19 of the '669 patent identifies the location of the opening as being "at the front end of the injector," and claims 1, 8, and 15 of the '261 patent refer, respectively, to the opening as being located "on the front [of the injector]," "at the front of the injector," and "on" the injector. Claim 27 of that patent refers to the injector housing as having "a tubular member extending forwardly from the front thereof and having a cylindrical bore therein forming the syringe receiving opening." In each case, the claim specifies the location and structure of the opening while making no mention of a pressure jacket.

In common usage, an opening is simply an aperture, and nothing in the '669 and '261 patents indicates that the term "opening" should be understood to carry with it the requirement that it must always be located in the front of a pressure jacket. Accordingly, contrary to the district court, we find no ambiguity in the term "opening" and no reason to resolve the purported ambiguity by reading that term restrictively. We therefore turn to Medrad's more general argument that the specification and the prosecution history demonstrate that the invention as a whole was limited to an injector system using a pressure jacket.

B

Medrad argues that because all the embodiments described in the common specification of the '669 and '261 patents feature pressure jackets, the claims of those patents must be construed as limited to devices that use pressure jackets. In Medrad's words, when "the subject matter claimed in the patent-in-suit is the *only* subject matter described . . . that subject matter is the invention, and not simply a 'preferred embodiment' of a broader invention."

There are several answers to Medrad's argument. The first is that this court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. *See ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1091 (Fed.Cir.2003); *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1377 (Fed.Cir.2003); *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1373 (Fed.Cir.2003); *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204-05 (Fed.Cir.2002); *Teleflex, Inc. v. Ficosa N. Am.*

Corp., 299 F.3d 1313, 1327 (Fed.Cir.2002); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 n. 14 (Fed.Cir.1985) (en banc). Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using "words or expressions of manifest exclusion or restriction." *Teleflex*, 299 F.3d at 1327.

For example, in *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed.Cir.2003), the court interpreted the term "remote" broadly to include surgical procedures performed with the surgeon present in the same room as the patient, although the written description only described performing the surgical procedure without the surgeon present in the same room as the patient, because "[n]o statement in the written description [] constitute[d] a limitation on the scope of the invention." Likewise, in *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed.Cir.2003), despite the fact that the specification discussed only a single embodiment, we held that it was improper to read a specific order of steps into method claims because the specification "nowhere [included] any disclaimer of any other order of steps, or any prosecution history indicating a surrender of any other order of steps."

In support of its contention that the claims are limited to the embodiments described in the specification, Medrad cites several of this court's cases, including *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed.Cir.2001), and *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed.Cir.1999). None of the cited cases supports Medrad's argument, however.

In *SciMed,* we stated that when the specification "makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." 242 F.3d at 1341. We concluded in *SciMed* that the claim to a two-part lumen used in balloon dilatation catheters was limited to coaxial lumens and did not include dual, side-by-side lumens. We reached that conclusion based on an explicit disclaimer of the side-by-side structure, not the mere absence of any reference to that structure in the specification. Thus, the specification discussed only the coaxial lumen structure, it characterized the side-by-side structure as inferior, and it concluded that the coaxial lumen structure was used in "all embodiments of the present invention contemplated and disclosed herein." *Id.* at 1343. Based on the language of the specification, we concluded that the *SciMed* case presented "a clear case of the disclaimer of subject matter that, absent the disclaimer, could have been considered to fall within the scope of the claim language." *Id.* at 1344. Unlike in *SciMed,* the specification in this case contains no disclaimer; all that Medrad can point to in the common specification of the '669 and '261 patents is the absence of any embodiment that lacks a pressure jacket.

In *Wang,* the claim term at issue was the term "frame" as applied to a computer application. Although the parties agreed that in the abstract that term could refer to both "character based systems" and "bit-mapped display systems," the court noted that in the context of the patent in suit, the term referred only to "character-based systems."

197 F.3d at 1382. After a close examination of the specification, the court concluded that the specification "would not be . . . understood by a person skilled in the field of the invention" to describe bit-mapped display systems as included in the applicant's invention. *Id.* Moreover, the prosecution history of the patent in suit in *Wang* showed that the inventors disclaimed a claim construction that would encompass bit-mapped display systems. *Id.* at 1383-84. *Wang* therefore does not stand for the proposition that if a patent specification describes only a particular embodiment, the claims must be limited to that subject matter. We have never read *Wang Labs* to stand for so broad a proposition, *see Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1305 (Fed.Cir.2003); *Altiris,* 318 F.3d at 1373; *Teleflex,* 299 F.3d at 1327; *SciMed,* 242 F.3d at 1341, and we decline Medrad's invitation to adopt such a rule today.

In other cases cited by Medrad, we have held that the embodiments of the invention set forth in the specification constituted the invention itself, in spite of claim language that could, in the abstract, be interpreted more broadly. *See Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1139-40 (Fed.Cir.2003); *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-83 (Fed.Cir.2000); *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed.Cir.2000); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1301-02 (Fed.Cir.1999); *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed.Cir.1996); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n,* 75 F.3d 1545, 1550-51 (Fed.Cir.1996). In each of those cases, however, there were specific reasons dictating a narrow claim construction beyond the mere fact that the specification disclosed only a single embodiment or a particular structure. Thus, in *Watts,* the court held that the applicants specifically "limit[ed] the invention" to

particular structures by specifying that the invention uses those structures, and further limited the scope of the invention by distinguishing close prior art in the prosecution history. 232 F.3d at 883. Likewise, in the *Cultor* and *Biogen* cases, the court construed the pertinent claim language restrictively based on an express limiting definition of that language in the specification, *Biogen,* 318 F.3d at 1140, as well as the fact that the inventors had "repeatedly distinguished their invention from the prior art" by characterizing their invention narrowly, *Cultor,* 224 F.3d at 1330. As the court explained in *Cultor,* "Whether a claim must, in any particular case, be limited to the specific embodiment presented in the specification, depends in each case on the specificity of the description of the invention and on the prosecution history. . . . Claims are not correctly construed to cover what was expressly disclaimed." *Id.* at 1331.

The court employed the same approach in the *Toro, General American Transportation,* and *Modine Manufacturing* cases. In those cases, this court interpreted the pertinent claim language narrowly, not merely because the specification did not describe a broader embodiment, but because the specification, claim, or prosecution history made clear that the invention was limited to a particular structure. *See Toro,* 199 F.3d at 1301 (noting that the specification described particular structure as "important to the invention"); *Gen. Am. Transp.,* 93 F.3d at 770 (holding that claim language and specification made clear that openings "adjacent each of said side walls and end walls" of a rail car required the openings to be adjacent to all four walls of the railcar); *Modine,* 75 F.3d at 1551 (claim limited to a particular numerical range when

broader range was surrendered during prosecution by amendment of the specification).

In this case, the specification does not describe the invention as limited to embodiments having pressure jackets, and none of the other reasons that have been invoked for giving claims a narrow reading are present. Although all the embodiments described in the common specification of the '669 and '261 patents include a pressure jacket, the written description does not contain a clear disavowal of embodiments lacking a pressure jacket. Medrad relies on several passages from the specification in which the applicants described an embodiment that uses a pressure jacket. Those passages, however, do not expressly or by clear implication restrict the scope of the invention to injectors using a pressure jacket. The abstract of the patents states that an "animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is loadable and unloadable into and from the injector through the open front end of a pressure jacket of the injector." Although that language can reasonably be understood as constituting a general description of the invention, the quoted passage does not suggest that a pressure jacket is an essential component of the invention, nor is there any language in that passage, or elsewhere in the specification, that disclaims the use of the invention in the absence of a pressure jacket.

The other passages from the specification on which Medrad relies provide even less support for Medrad's argument that the claims must be limited to the described embodiments. In the Summary of the Invention, the patent describes one of the objectives of the invention as being "to provide an injector wherein a used syringe can be

removed and a new one inserted in the injector without retraction of the drive from the pressure jacket, in most applications," and adds that it is "a further objective of the invention to allow for the removal of the used syringe from the jacket without disconnection of the injector tube from the syringe nozzle." '669 patent, col. 2, ll. 32-39; '261 patent, col. 2, ll. 29-36. Later in the Summary of the Invention, the patents provide: "According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is provided in the front end of the pressure jacket." '669 patent, col. 2, l. 64, to col. 3, l. 1; '261 patent, col. 2, ll. 61-65. Those passages, although focusing on the use of the invention in conjunction with pressure jackets, do not disclaim the use of the invention in the absence of a pressure jacket. The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives. *See Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1367 (Fed.Cir.2003); *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1355 (Fed.Cir.2003); *Honeywell Inc. v. Victor Co. of Japan, Ltd.*, 298 F.3d 1317, 1325-26 (Fed.Cir.2002). Moreover, the reference to the "principles of the present invention" as providing for "an angiographic injector" with a syringe that can be "loaded into and removed from the injector pressure jacket," does not limit the invention to devices that have pressure jackets any more than it limits the invention to injectors that are used for angiography. This case is therefore governed by the principle that "[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a

particular way does not mean that the scope of the invention is limited to that context." *Northrop Grumman,* 325 F.3d at 1355; *accord Brookhill-Wilk,* 334 F.3d at 1301; *Teleflex,* 299 F.3d at 1328.

C

The second reason for rejecting Medrad's argument is that the prosecution history of the '669 and '261 patents is squarely contrary to its contention that all the claims of those two patents require injectors that use pressure jackets. The applications that matured into the '669 and '261 patents derived from the '110 application. In the prosecution of each of those applications, the applicants replaced claims that had included references to a pressure jacket with a new set of claims, many of which did not include the pressure jacket limitation. The omission of reference to a pressure jacket in many of the claims of the applications that matured into the '669 and '261 patents is a strong indication that the applicants intended those claims to reach injectors that did not use pressure jackets. Moreover, in a paper filed during the prosecution of the '261 patent, the applicants clearly stated that "[i]n the claims as amended herein, the locking structure is not necessarily at the front end of the syringe, nor is there necessarily a pressure jacket."

Both Medrad and the district court agree that, during the prosecution of the '669 and '261 patents, the applicants learned about Medrad's jacketless injector and sought to omit reference to the pressure jacket in the asserted

claims in order to encompass Medrad's injector.[2] Thus, there is no dispute as to the applicants' intentions with respect to the meaning of the asserted claims – the claims were amended to include methods and devices in which pressure jackets are not used. The only remaining question is whether the applicants failed in their effort and the pressure jacket limitation remained a part of all of the claims, even those from which the reference to the pressure jacket had been removed. We are unpersuaded by that argument, particularly in light of the applicants' express statement in the prosecution history of the '261 patent that there is not "necessarily a pressure jacket" in the claimed devices.

D

Apart from the literal language of the asserted claims and the prosecution history, the doctrine of claim differentiation provides significant added support for Liebel's claim construction. As we noted above, the '669 and '261 patents both contain claims that explicitly recite the requirement of a pressure jacket and that are dependent

[2] The district court recognized that it is not improper for an applicant to broaden his claims during prosecution in order to encompass a competitor's products, as long as the disclosure supports the broadened claims. *See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed.Cir.1988) (holding that it is not improper "to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application"). If the disclosure does not support the broadened claims, the applicant will not be accorded priority based on the original disclosure, and the claims may be invalidated. *See Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed.Cir.2000); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed.Cir.1997).

from asserted independent claims that do not contain such a requirement. In the '669 patent, asserted claim 10 recites a method of loading a tubular replacement syringe into a high pressure power injector without reference to a pressure jacket. Claim 14, which depends from claim 10, adds four limitations that recite the use of a pressure jacket in the process of inserting the syringe. A comparison of claims 10 and 14 makes clear that the only significant distinction between the two is that claim 14 requires the use of a pressure jacket.

Similarly, asserted claims 1 and 18 of the '261 patent claim syringes and front-loadable power injectors without reference to pressure jackets. By contrast, claims 2 and 19, which depend from claims 1 and 18, respectively, expressly recite the use of a pressure jacket. Again, a comparison of the independent and dependent claims shows that the dependent claims differ from the independent claims only with regard to the presence of a pressure jacket in the dependent claims.

The juxtaposition of independent claims lacking any reference to a pressure jacket with dependent claims that add a pressure jacket limitation provides strong support for Liebel's argument that the independent claims were not intended to require the presence of a pressure jacket. As this court has frequently stated, the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim. *See Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed.Cir.2001); *Comark*, 156 F.3d at 1187. Although that presumption can be overcome if the circumstances suggest a different explanation, or if the evidence favoring a different claim construction is strong, the presumption is unrebutted in

this case, as Medrad has offered no alternative explanation for why the "pressure jacket" limitation is found in the dependent claims but not in the corresponding independent claims. In such a setting, where the limitation that is sought to be "read into" an independent claim already appears in a dependent claim, the doctrine of claim differentiation is at its strongest. *See Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302-03 (Fed.Cir.2003) (the presumption that an independent claim does not have a limitation that is introduced for the first time in a dependent claim "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim"); *Wenger*, 239 F.3d at 1233 ("Claim differentiation . . . is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims."); *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed.Cir.1985). The doctrine thus substantially undermines Medrad's contention that all of the claims of the '669 and '261 patents require the presence of a pressure jacket, even though the express requirement of a pressure jacket is found only in certain claims and not in any of the claims asserted in this case.

E

In support of its claim construction, the district court stated, without elaboration, that it is "unlikely that the specification, which was drafted for claims that disclosed an injector that included a pressure jacket, would describe an injector that does not require a pressure jacket, much

less enable one skilled in the art to make and use such a device." Medrad supplements that observation by arguing, also without elaboration, that if the asserted claims are not construed to require a pressure jacket, those claims "would be of doubtful validity."

This court has frequently alluded to the "familiar axiom that claims should be so construed, if possible, as to sustain their validity." *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed.Cir.1999) (internal quotation marks omitted). At the same time, however, the court has "admonished against judicial rewriting of claims to preserve validity." *Id.* Accordingly, unless the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous, the axiom regarding the construction to preserve the validity of the claim does not apply. *See AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1243 (Fed.Cir.2003) ("That axiom is a qualified one, dependent upon the likelihood that a validity-preserving interpretation would be a permissible one."); *Generation II Orthotics Inc. v. Med. Tech. Inc.*, 263 F.3d 1356, 1365 (Fed.Cir.2001) ("[C]laims can only be construed to preserve their validity where the proposed claim construction is 'practicable,' is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims."); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1309 (Fed.Cir.2000) ("having concluded that the amended claim is susceptible of only one reasonable construction, we cannot construe the claim differently from its plain meaning in order to preserve its validity").

A case that is closely analogous to this one is *Texas Instruments Inc. v. United States International Trade Commission*, 871 F.2d 1054 (Fed.Cir.1989). In that case, the applicant amended a claim during prosecution, seeking

broader claim coverage that would reach a competitor's product. The International Trade Commission, in order to preserve the validity of the claim, construed the claim as being limited to the meaning it had before it was amended. This court reversed the Commission, holding that the amended claim should have been construed in accordance with the language of the amendment. The court stated: "Ambiguous claims, whenever possible, should be construed so as to preserve their validity. . . . This rule of construction, however, does not justify reading into a claim a limitation that it does not contain and that the patentee deleted from the claim during prosecution." *Id.* at 1065. The court explained that it was not improper for the applicant to amend the claim in order to cover a competitor's product that the applicant's attorney has learned about during the prosecution of the application; the court then added that it was "not permissible for the [Commission], in order to preserve the validity of the claims, to rewrite them to add a limitation that the patentee had eliminated during prosecution, and then hold that the challenged devices . . . did not infringe the rewritten claims." *Id.*

In this case, the applicants in effect drafted particular claims of the applications that matured into the '669 and '261 patents so as to omit the pressure jacket limitation that had been present in all of the claims of the parent '110 application. As in *Texas Instruments,* it would be improper to disregard the effect of that action on the scope of those claims simply because the claims, if broadly construed, might be vulnerable to a challenge to their priority and validity. Rather, because the proper construction of the claims is clear, the questions of priority and

validity are separate issues that must be separately addressed on remand.

In sum, the claims do not expressly require pressure jackets, and Medrad points to no clear disavowal of claim scope in either the written description or the prosecution history. In fact, the prosecution history indicates that the asserted claims were added to cover devices that lacked pressure jackets. For those reasons, we conclude that the district court erred in construing the claims at issue to require pressure jackets. Summary judgment of noninfringement of the '669 and '261 patents was therefore improper.

III

Medrad's appeal with respect to the asserted claims of the '612 and '197 patents turns on the proper construction of the term "physical indicia" and the relationship of the physical indicia to the properties of a syringe. Claim 7 of the '197 patent is representative of the asserted claims of the '612 and '197 patents. It provides as follows:

> An injector and syringe, comprising
>
> a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the amount of fluid in the syringe,
>
> a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and
>
> a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

> a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the amount of fluid in said syringe using said electrical signal and the tracked location of said motor.

A

Each of the asserted claims, except for claim 25 of the '197 patent, requires that the syringe possess "physical indicia related to" a property of the syringe. For example, claim 7 of the '197 patent, quoted above, recites "physical indicia related to the amount of fluid in the syringe," while other claims recite physical indicia related to "the distance of the plunger from an end of said syringe," "the end of travel position of an injector ram," "the range of travel of an injector ram," and "the capacity of the syringe."

Medrad argues that we should construe the term "physical indicia" as limited to features that indicate the length of the extender. To support its position, Medrad asserts that the only reference to the "physical indicia" limitation in the specification describes the "physical indicia" as providing information as to the length of the extender:

> In preferred embodiments, the offset value may be computed by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value. The controller may be configurable so that this query is not made (for example, if the injector will not be used

> with pre-filled syringes, and therefore the offset value will not change). Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

'612 patent, col. 3, l. 62, to col. 4, l. 3; '197 patent, col. 3, l. 61, to col. 4, l. 2.

The claim language itself does not limit "physical indicia" to indicia related to the length of the extender. Instead, the various claims explicitly state that the physical indicia are related to a variety of properties, such as the amount of fluid in the syringe, the distance of the plunger from the end of the syringe, the distance to the end of the plunger's travel position, and the range of travel of the ram. Medrad thus must overcome the "'heavy presumption' that [the claims] mean what they say." *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed.Cir.2002); *Teleflex*, 299 F.3d at 1325 ("We indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning."). As we explained above, it is improper to read limitations from a preferred embodiment described in the specification – even if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited. *See ACTV*, 346 F.3d at 1088; *Brookhill-Wilk*, 334 F.3d at 1301; *Altiris*, 318 F.3d at 1371, 1373; *Teleflex*, 299 F.3d at 1327. Although the passage Medrad cites describes an embodiment in which the physical indicia are related to the length of an extender, Medrad does not point to any language in the specification that expresses an intention to limit the scope of the term "physical indicia" to that embodiment.

Nor does the prosecution history support Medrad's narrow reading of the asserted claims. During the prosecution of the application that matured into the '197 patent, the examiner rejected the claims as lacking support for physical indicia related to properties other than the length of the extender. The applicants responded by explaining that various properties, such as the amount of fluid in the syringe, could be calculated from the information as to the length of the extender. The applicants went on to explain, however, that

> although the supporting specific embodiment of the invention found in the specification is disclosed in the context of compensating for the presence of a plunger extender attached to the plunger, the independent claims do not necessarily require a plunger extender, but rather are directed generally to using information from indicia on a syringe, to compensate for syringes having differing initial plunger positions, differing initial amounts of fluid, differing end-of-travel positions or ranges of travel for the ram.

Far from a clear disavowal of claim scope, the quoted passage makes clear that the application contemplated that the claims of the '197 patent would encompass "physical indicia" related to properties other than the length of an extender.

Moreover, Medrad's own version of the prosecution history of the '612 and '197 patents cuts against reading the claims at issue restrictively. The original claims in the applications for the two patents limited the term "physical indicia" to features indicating the "length of the extender" and excluded features indicating other syringe properties such as "the capacity of the syringe." According to Medrad,

when the applicants learned of Medrad's injectors they amended the claims at issue in an effort to encompass Medrad's injectors, as they did with respect to the "pressure jacket" issue. That characterization of the prosecution history, however, is unhelpful to Medrad's claim construction argument: By broadening the claims to cover Medrad's devices, the applicants covered physical indicia other than those indicating the length of an extender. The district court therefore correctly concluded that the term "physical indicia" is not limited to indicia related to the length of an extender.

Medrad further suggests in passing that the broad reading of "physical indicia" given by the district court would render the asserted claims of the '612 and '197 patents invalid for lack of a sufficient written description or enablement. As we discussed above, however, the canon that claims should be construed to preserve their validity, if possible, applies only if the scope of the claims is ambiguous. The asserted claims at issue in this case clearly cover more than the "indicia indicating the length of the extender." We therefore may not interpret the claims narrowly because of concerns about their possible invalidity. Rather, the issue of invalidity must be addressed head-on in the remand proceedings where the questions of priority, and the adequacy of the written description and enablement, will be directly presented.

B

The district court construed the claim term "related to" as requiring "the physical indicia [to be] the actual syringe properties or [indicia that can be] directly used in the computation of the various syringe properties without

reference to some other source of information." The court found the grounding for that construction in the language of the claims themselves. For example, the court reasoned that claim 7 of the '197 patent, reproduced above, requires that a detector ascertain the physical indicia and generate an electrical signal representative of those indicia. A control circuit then computes the value of the property in question, here the amount of fluid in the syringe, using that electrical signal. The district court determined that the control circuit must use the signal generated by the detector, rather than a signal generated by the control circuit, to compute the value of the property in question. The court thus construed the claims as requiring a direct relationship between the physical indicia and the property to which the physical indicia are related. That direct relationship, the district court reasoned, would exclude products, such as the Medrad injectors, that "indirectly" compute the value of the syringe property by using the electrical signal to reference a look-up table.

The language of the claims at issue does not support the interpretation adopted by the district court. The term "related to" by itself does not limit the relationship between the physical indicia and the properties in question to a direct relationship. The issue, then, is whether the claim language setting forth how the control circuit must use the electrical signal confines the relationship between the physical indicia and the syringe properties to a direct relationship. The exemplary claim quoted above requires that the "control circuit compute[] the amount of fluid in said syringe using said electrical signal." That language does not specify that the control circuit must use the electrical signal in any particular way. In the ordinary sense of the word "using," the act of employing the electrical signal to

obtain a syringe property value from a look-up table constitutes "using" the electrical signal to compute that syringe property value. Therefore, the very language relied on by the district court to restrict the scope of the claims at issue does not exclude an injector in which the control circuit uses the electrical signal to compute the syringe property indirectly, for example by using the electrical signal in conjunction with a look-up table.

Medrad asserts that during prosecution the applicants distinguished the '612 and '197 patent claims from prior art substantially similar to Medrad's accused devices and that the asserted claims therefore must be read restrictively. During prosecution of an application that matured into the '612 patent and that gave rise to a continuation that matured into the '197 patent, the examiner rejected the claims as obvious over two prior art references, McDaniel and Arthur. The McDaniel reference disclosed associating the type of syringe with its corresponding properties using a look-up table, while the Arthur reference disclosed a detector for detecting a bar code on a syringe. The examiner asserted that it would be obvious to combine the detector and bar coding of Arthur with the McDaniel device to arrive at Liebel's claims. The applicants overcame that rejection by arguing that McDaniel and Arthur should not be combined because they addressed different problems. Liebel argued that the bar code "indicia" in Arthur did not indicate any syringe properties at all, but rather provided information regarding the concentration of the medication in the syringe. McDaniel, according to Liebel, disclosed a mechanical system for determining the syringe type, such as by measuring the angle of the conical forward end of the syringe. Instead of arguing that McDaniel did not teach

detecting information "related to" syringe properties, Liebel argued that McDaniel did not teach detecting physical indicia at all. The applicants thus did not disclaim an "indirect" relationship between the physical indicia and the syringe properties.

Because both the plain language of the claims and the prosecution history do not support a claim construction limiting the relationship between the physical indicia and the syringe properties to a direct relationship, the district court erred in so ruling. It was therefore improper for the court to enter summary judgment of noninfringement of the asserted claims of the '612 and '197 patents. The district court will have to reconsider the infringement claims in light of the claim construction we have set forth above.

In view of its claim construction ruling, the district court did not need to analyze claim 25 separately from the other asserted claims of the '612 and '197 patents, other than to note that the language of claim 25 differs somewhat from that of the other claims. To the extent that Liebel continues to assert claim 25 on remand, the district court will have an opportunity to consider the proper construction of that claim in light of our interpretation of the language of the other asserted claims of the '612 and '197 patents.

IV

With respect to disposition, Liebel argues that we should direct the district court to grant summary judgment in its favor. We decline to do so. It is rare for a reviewing court, upon reversing the grant of summary judgment in favor of one party, to direct the entry of

summary judgment in favor of the other, and this is not one of those rare instances in which such a course would be appropriate. The district court is far more familiar with the record in this case than we are and is in a much better position to determine whether, based on the claim construction issues addressed above, summary judgment in Liebel's favor would be appropriate. Moreover, Medrad points out that there are unresolved issues of infringement that would have to be addressed before a final judgment of infringement could properly be entered. We therefore reverse the entry of summary judgment in Medrad's favor, but we do not direct the entry of summary judgment for Liebel.

As to Medrad's cross-appeal, we agree that Medrad's invalidity counterclaims are not moot. Because we have reversed the order granting summary judgment of noninfringement, the legal basis for the district court's mootness ruling is no longer in place. The invalidity counterclaims are therefore again presented for decision, and we assume that the district court will address the counterclaims on remand if Medrad continues to press them.

REVERSED and REMANDED.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

LIEBEL-FLARSHEIM COMPANY, and MALLINCKRODT INC.	)	Civil Action No. C-1-98-858
Plaintiffs,	)	Judge Sandra S. Beckwith Magistrate Judge Jack Sherman, Jr.
v.	)	
MEDRAD, INC.,	)	
Defendant.	)	

JUDGMENT IN A CIVIL CASE

(Filed Oct. 31, 2002)

This is an action for infringement of U.S. Patent Nos. 5,456,669, 5,658,261, 5,662,612 and 5,928,197; violation of the antitrust laws of the United States; and tortious interference with existing and prospective business relations.

On October 18, 2001, this Court entered an Order (Doc. No. 247) granting summary judgment of non-infringement for defendant Medrad, Inc. on Counts I and II of the Fourth Amended Complaint (Doc. No. 30) with respect to U.S. Patent Nos. 5,456,669 and 5,658,261.

On February 19, 2002, this court entered an Order (Doc. No. 271) granting summary judgment of non-infringement for defendant Medrad, Inc. on Counts III and IX of the Fourth Amended Complaint (Doc. No. 30).

On May 14, 2002, this Court entered an Order (Doc. No. 284) dismissing, without prejudice, as moot defendant Medrad, Inc.'s counterclaims of invalidity, unenforceability

and unclean hands, laches, and estoppel as stated in Counterclaim paragraph 10, 11 and 12 of its Amended Answer and Amended Counterclaim (Doc. No. 82).

On October 9, 2002, the parties fully and finally settled Counts IV-VIII of the Fourth Amended Complaint.

It is hereby ORDERED AND ADJUDGED that judgment is entered for defendant Medrad, Inc. on Counts I and II of the Fourth Amended Complaint for the reasons set forth in the Order entered October 18, 2001 (Doc. No. 247), that judgment is entered for defendant Medrad, Inc. on Counts III and IX of the Fourth Amended Complaint for the reasons set forth in the Order entered February 19, 2002 (Doc. No. 271), that Counts IV-VIII are dismissed with prejudice by agreement and that defendant Medrad, Inc.'s counterclaims as to invalidity, unenforceability and unclean hands, laches and estoppel as stated in its Amended Answer and Amended Counterclaim are dismissed without prejudice as moot for the reasons set forth in the Order entered May 14, 2002 (Doc. No. 284).

Dated this 30th day of October, 2002.

Clerk of Court.

By: /s/ Sandra S. Beckwith

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

Liebel-Flarsheim Co.	:	
Plaintiff,	:	
vs.	:	Case C-1-98-858
Medrad Inc.,	:	
Defendant.	:	

ORDER

(Filed Oct. 18, 2001)

This matter is before the Court on multiple motions for partial summary judgment. In this Order, the Court will address the motions filed under Doc. Nos. 57, 162, 164, 167, 168, and 169.

I. GENERAL BACKGROUND

The patents at issue in this case, United States Patent No. 5,456,669 ("the '669 patent"), United States Patent No. 5,658,261 ("the '261 patent"), United States Patent No. 5,662,612 ("the '612 patent"), and United States Patent No. 5,928,197 ("the '197 patent"), are part of a series of patents that relate to medical devices known as powered injectors which deliver contrast agents[1] from a syringe into a patient's bloodstream for

[1] In a number of diagnostic procedures, such as angiography, computed tomography, ultrasound, and magnetic resonance imaging, the image obtained may be substantially enhanced through the use of a

(Continued on following page)

certain medical diagnostic procedures. (Doc. No. 30, Exhs. 1-4). The specific patents at issue in this case involve two developments in the field of power injectors (1) the front-loadable power injector and (2) automatic control of the plunger driver during the injection process.

A. Front-Loadable Power Injectors

When the original '110 application was filed, the powered injectors sold by both Plaintiff Liebel-Flarsheim Company ("L-F") and Defendant Medrad, Inc. ("Medrad") required that the syringe be inserted in the injector by a breech-load method. However, loading of the syringe by the breech-load method was cumbersome, time-consuming, and inefficient, and this method presented a cleanliness problem and posed a safety hazard.

In the late 1980's, L-F began a brainstorming process that culminated in the invention of a front-loadable powered injector system that eliminated the disadvantages inherent in the breech-loading power medical injectors and provided benefits in terms of use, speed, efficiency, sterility, and cleanliness.

On June 7, 1991, L-F filed its first patent application, Application Serial No. 07/712,110 ("the '110 application") on its CT injection system with a front-loadable syringe. (Doc. No. 57, Exh. 7). The '669 and '261 patents, entitled "Method of Front Loading an Injector and Injecting Fluid into Animals Therewith" and "Disposable Front Loadable Syringe," respectively, issued from a series of divisional

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contrast agent, *i.e.*, a pharmaceutical that is injected into the body of the patient.

applications originating with the '110 application.[2] (Doc. No. 30, Exhs. 1, 2).

At the time the '110 application was filed, all power injectors that used disposable plastic syringes had components known as pressure jackets, which are hollow cylindrical tubes attached to the front of the injector that surround the syringe. (Doc. No. 57, Exh. 8 – Goethel Depo., p. 465, Exh. 9 – Fago Depo., p. 103, Exh. 13, Dieterlen Depo., p. 141, Exh. 14 – Neer Depo, p. 135). During the development of its front-loadable injector system, L-F considered the idea of eliminating the pressure jacket. (Doc. No. 57, Exh. 9 – Fago Depo., p. 83, Exh. 13 – Dieterlen Depo., p. 63). After running several preliminary tests, L-F chose not to develop a jacketless injector system. (Doc. No. 57, Exh. 9 – Fago Depo., pp. 83-84, Exh. 13 – Dieterlen Depo., p. 63).

At a trade show in November in 1992, Medrad introduced the first pressure jacketless, front-loading CT injector system for disposable syringes. (Doc. No. 57, Exh. 11, ¶ 2). This system neither required nor used a pressure jacket. (*Id.*). All of Medrad's injector systems that were or are front loaded did not and do not use or require a pressure jacket. (*Id.* at ¶ 4). After Medrad introduced its jacketless injector, L-F amended the '669 and '261 patent

[2] The patent application for the '669 patent was filed on November 30, 1993, and issued on October 5 1995. The patent application for the '261 patent was filed on April 6, 1995, and issued on August 19, 1997. Because the '669 and '261 were divisional applications originating with the '110 application, they have an effective filing date of June 7, 1991, the filing date of the '110 applications. Furthermore, as divisional applications, the '669 and '261 patents have the same specifications and drawings.

applications, removing references to a pressure jacket in certain claims.[3] (Doc. No. 57, Exhs. 22, 26).

B. Automatic Control of Plunger Drivers

On June 26, 1995 and August 28, 1997, L-F filed patent applications that issued as the '612 patent and the '197 patent, respectively, relating to the automatic control of plunger drives in powered medical injector systems.[4] (Doc. 30, Exhs. 3, 4). At the time the patents were filed, the use of pre-filled disposable syringes was a recent advancement in the field of medical injector systems. These pre-filled syringes differed in capacity depending upon the medical procedure being performed.

The '612 and '197 patents, both titled "Controlling Plunger Drives for Fluid Injections in Animals", disclose a powered medical injector that automates the injection of pre-filled syringes. (Doc. No. 30, Exhs. 3, 4). The injector claimed in the patents includes structure and control circuitry that detects physical indicia on a syringe that relates to physical properties of the syringe. Based on these physical properties, the control circuitry of the injector automatically controls the injection process.

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[3] The '669 patent was amended on September 12, 1994, and the '261 patent was amended on April 6, 1995.

[4] The '612 patent issued on September 2, 1997 and the '197 patent issued on July 27, 1999. The '612 and '197 patents are continuations of a patent that was filed on November 27, 1993, but was subsequently abandoned. (Doc. No. 167, Exh. 4). Therefore, the '612 and '197 patents claim an effective filing date of November 24, 1993. Furthermore, as continuation applications, the '612 and '197 patents have the same specifications and drawings.

L-F initiated this lawsuit on November 13, 1998, claiming that Medrad, through its manufacture, use, marketing, and/or sale of various injectors and syringes, infringed, contributorily infringed, and/or induced infringement of the '669, '261, '612, and '197 patents. (Doc. Nos. 1, 4, 5, 23, 30). Medrad denied L-F's claims and counterclaimed seeking a declaratory judgment that Medrad does not infringe the '669, '261, '612, and '197 patents, that such patents are invalid, that such patents are void and unenforceable due to L-F's inequitable conduct, and that L-F is precluded from asserting its claims by virtue of unclean hands, laches and/or equitable estoppel. (Doc. Nos. 24, 25, 39).

Numerous partial summary judgment motions have been filed in this matter, including a motion for claim construction. Accordingly, on July 23, 2001, this Court conducted a *Markman* hearing at which counsel for both parties presented evidence. The Court is now prepared to rule on the following motions for partial summary judgment:

1. Plaintiff's Motion for Partial Summary Judgment of Claim Construction (Doc. 164)

2. Defendant's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the Asserted Claims of the '669 and '261 Patents (Doc. 168)

3. Defendant's Motion for Partial Summary Judgment of Invalidity and Non-Infringement of the Asserted Claims of the '669 and '261 Patents (Doc. 57)

4. Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612

and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. 162)

5. Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. 167).

6. Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. 169).

II. SUMMARY JUDGMENT STANDARD

Summary Judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The party opposing a properly supported summary judgment motion "'may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.'" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (quoting *First Nat'l Bank of Arizona v. Cities Serv. Co.*, 391 U.S. 253 (1968)). The Court is not duty bound to search the entire record in an effort to establish a lack of material facts. *Guarino v. Brookfield Township Trs.*, 980 F.2d 399, 404 (6th Cir. 1992); *Inter-Royal Corp. v. Sponseller*, 889 F.2d 108, 111 (6th Cir. 1989), *cert. denied, Superior Roll Forming Co. v. Inter-Royal Corp.*, 494 U.S. 1091 (1990). Rather, the burden is on the non-moving party to "present affirmative evidence to defeat a properly supported motion for summary judgment. . . ," *Street v. J.C. Bradford & Co.*, 886 F.2d 1472,

1479-80 (6th Cir. 1989), and to designate specific facts in dispute. *Anderson*, 477 U.S. at 250. The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Electric Industries Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The court construes the evidence presented in the light most favorable to the non-movant and draws all justifiable inferences in the non-movant's favor. *United States v. Diebold Inc.*, 369 U.S. 654, 655 (1962).

The court's function is not to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial. *Anderson*, 477 U.S. at 249. The Court must assess "whether there is the need for trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Id.* at 250. "If the evidence is merely colorable, . . . , or is not significantly probative, . . . , the court may grant judgment." *Anderson*, 477 U.S. at 249-50. (citations omitted). The Supreme Court has held that:

> The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict . . .

Id. at 252. The "'mere possibility'" of a factual dispute will not suffice. *Mitchell v. Toledo Hospital*, 964 F.2d 577, 582 (6th Cir. 1992) (quoting *Gregg v. Allen-Bradley Co.*, 801 F.2d 859, 863 (6th Cir. 1986)).

Summary judgment is not appropriate simply because the weight of the evidence favors the moving party. *Poller v. Columbia Broadcasting Systems, Inc.*, 368 U.S. 464, 472 (1962). The issue of material fact required "to entitle a party to proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Cities Serv. Co.*, 391 U.S. at 288-89.

Although summary judgment must be used with extreme caution since it operates to deny a litigant his day in court, *Smith v. Hudson*, 600 F.2d 60, 63 (6th Cir. 1979), (citations omitted), *cert. dismissed*, 444 U.S. 986 (1979), the United States Supreme Court has stated that the "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (citations omitted).

III. PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF CLAIM CONSTRUCTION (DOC. 164)

In this motion, L-F moves the Court for construction of the following claim terms and claim language:

- "syringe receiving opening" or "opening"
- "high pressure"
- none of the asserted claims of the '669 patent and none of the asserted claims of the

'261 patent requires that the injector include a pressure jacket

- "physical indicia"
- "motor" and "tracks" the location of said motor"

(Doc. No. 164.) Medrad has filed a memorandum in opposition (Doc. No. 172) to which L-F has filed a reply (Doc. No. 182).[5] [6]

A. Law on Claim Construction

When construing a patent claim, the court must first consider the intrinsic evidence, i.e., the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir. 1996);

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[5] The Court also reviewed Medrad's Motion to File a Sur-Reply (Doc. No. 191) and L-F's memorandum in opposition (Doc. No. 197). Additionally, the Court reviewed L-F's Motion to File a Post-Claim Construction Hearing Memorandum (Doc. No. 223), Medrad's memorandum in opposition (Doc. No. 230), and L-F's reply (Doc. No. 236).

[6] L-F and Medrad also presented arguments addressing the issue of interpretation of the claim terms in Medrad's Motion for Partial Summary Judgment of Invalidity and Non-infringement of the '669 and '261 Patents (Doc. No. 57), L-F's Response to that motion (Doc. No. 84), and Medrad's Reply (Doc. No. 99); in Medrad's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the '612 and '197 Patents (Doc. No. 167), L-F's Response to that motion (Doc. No. 174), and Medrad's Reply (Doc. No. 184); in Medrad's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the '669 and '261 Patents (Doc. No. 168); L-F's Response to that motion (Doc. No. 175), and Medrad's Reply (Doc. No. 187); in L-F's Motion for Partial Summary Judgment of Infringement (Doc. No. 169), Medrad's Response to that motion (Doc. No. 176), and L-F's Reply (Doc. No. 185). The Court reviewed the arguments presented in each of these documents when construing the claim terms.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir. 1995), *aff'd*, 517 U.S. 370 (1996)). Extrinisic evidence may be considered if the intrinsic evidence does not resolve an ambiguity in a challenged claim. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed.Cir. 1999). However, "the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Karlan Technology Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971 (Fed.Cir. 1999). The court may receive extrinsic evidence to educate itself about the invention and the relevant technology. *Id.*

In claim construction, the court first considers the language of the claim. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed.Cir. 2001); *Johnson Worldwide Assocs.*, 175 F.3d at 989. The court should give claim terms their ordinary and customary meaning unless the specification or prosecution history provides a special, different meaning or definition. *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed.Cir. 2000); *see Johnson Worldwide Assocs.*, 175 F.3d at 989. The court will ordinarily give general descriptive terms their full meaning and will not add modifiers to broad terms standing alone. *Johnson Worldwide Assocs.*, 175 F.3d at 989. The court "must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms. *Id.* Where certain words have no specialized meaning to persons of skill in the art, "the ordinary meaning of those words to those skilled in the art controls . . . , unless the evidence indicates that the inventor used them differently." *See Karlin Technology*, 177 F.3d at 971; *Toro Co. v. White Consolidated Industries,*

Inc., 199 F.3d 1295, 1299 (Fed.Cir. 1999) (quoting *Hoechst Celanese Corp. v. B.P. Chemicals Ltd.*, 78 F.3d 1575, 1578 (Fed.Cir. 1996), *cert. denied*, 519 U.S. 911 (1996)).

In addition to interpreting a claim by the language used, the court also must read claims in view of the specification. *Markman*, 52 F.3d at 979 (citations omitted); *see Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir. 1998) (stating that because a court must understand and interpret the inventor's words as they would be understood and interpreted by a person in that field of technology, the court must review the same resources as that skilled person would review, *i.e.*, the patent specification and the prosecution history). The specification contains a written description of the invention that must enable a person of ordinary skill in the art to make and use the invention. *Markman*, 52 F.3d at 979. Furthermore, the description may define terms used in the claims. *See id.* The court reviews the specification to determine whether the patentee used terms in a manner consistent with their ordinary meaning. *DeMarini Sports, Inc. v. Worth Inc.*, 239 F.3d 1314, 1323 (Fed.Cir. 2001).

Although claims are interpreted in light of the specification, this does not mean that everything stated in the specification must be read into all the claims. *SRI Int'l v. Matsushita Electric Corp.*, 775 F.2d 1107, 1121 (Fed.Cir. 1985) (quoting *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed.Cir. 1983), *cert. denied*, 469 U.S. 835 (1984)). While the written description may help the court construe a claim term, the court may not read into the claim limitations, examples, or embodiments appearing only in the written description. *Kraft Foods*, 203 F.3d at 1366. "[I]nterpreting what is *meant* by a word *in* a claim 'is not to be confused with adding an extraneous limitation appearing in the

specification, which is improper.'" *Intervet America, Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed.Cir. 1989) (quoting *E.I. Du Pont De Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed.Cir. 1988), *cert. denied*, 488 U.S. 986 (1988)). The claims measure the invention. *SRI Int'l*, 775 F.2d at 1121 (citations omitted).

However, "'[c]laims are not interpreted in a vacuum but are part of and are read in light of the specification.'" *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1341 (Fed.Cir. 2001) (quoting *Slimfold Mfg. Co. v. Kinkead Industries, Inc.*, 810 F.2d 1113, 1116 (Fed.Cir. 1987)). "One purpose for reviewing the specification is to determine whether the patentee has limited the scope of the claims." *Watts v. XL Systems, Inc.*, 232 F.3d 877, 882 (Fed.Cir. 2000). "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *SciMed Life Systems*, 242 F.3d at 1341.

In addition to the specification, a court considers the prosecution history to determine the true meaning of the language used in the patent claim. *Markman*, 52 F.3d at 980. However, the court may not use the prosecution history to "'enlarge, diminish, or vary' the limitations in the claims." *Id.* (quoting *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 227 (1880)); *see also*, *Intervet America*, 887 F.2d at 1054. The court considers the prosecution history to determine whether or not the patentee made any express representations in obtaining the patent

regarding the scope and meaning of the claims. *DeMarini Sports*, 239 F.3d at 1323.

With these principles in mind, the Court will proceed with the requested claim construction of the '669, '261, '612, and '197 patents.

B. "Syringe Receiving Opening" or "Opening"/ Requirement of a Pressure Jacket

In this motion for partial summary judgment, L-F requests that the Court interpret the terms "syringe receiving opening" and "opening" as they appear in the asserted claims of the '669 and '261 patents.[7] As the following analysis demonstrates, the construction of these terms is closely intertwined with L-F's contention that the injector referenced in the asserted claims of the '669 and '261 patents does not require a pressure jacket. The Court will, therefore, analyze these issues together.

L-F proposes that the terms "syringe receiving opening" and "opening" refer to "an opening in an injector for receiving a syringe." (Doc. No. 164, p. 1). Medrad contends that the terms refer to the "open end of a pressure jacket." (Doc. No. 172, p. 16).

The difference in the parties' interpretations of these terms is significant. On the issue of non-infringement of the asserted claims, Medrad argues that the accused products do not infringe the '669 and '261 patents because both patent specifications describe an injector that requires a pressure

[7] The asserted claims are 10-11, 13, 16-19 of the '669 patent and 1, 8, 9, 11-13, 15-16, 18, 22, 27-28, 30-32, 34-37 of the '261 patent.

jacket.[8] (Doc. No. 57, p. 19). Medrad's accused injectors are jacketless. L-F, on the other hand, argues that the term "pressure jacket" does not appear in the asserted claims, and thus, the claims do not describe an injector that requires a pressure jacket. (Doc. No. 164, p. 23). In response, Medrad has argued that the asserted claims contain the terms "syringe receiving opening" or "opening," which, in order to preserve the validity of the patents, must be interpreted as the opening of a pressure jacket. (Doc. No. 57, p. 18). Therefore, according to Medrad, the claims describe a device that requires a pressure jacket. (*Id.*).

The Court begins its analysis where all claim construction begins – the language of the claim. *See Interactive Gift Express*, 256 F.3d at 1331. With respect to the asserted claims, "syringe receiving opening" and "opening" are described as follows:

- "a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim"
  '669 patent, Claim 10

- "an opening at the front end of the injector dimensioned to receive the back end of a disposable syringe . . . "
  '669 patent, Claim 19

[8] It should be noted that the '669 and '261 patents do not claim the invention of a front-loadable injector. Rather, the '669 patent claims a method of front loading an injector and injecting fluid and the '261 patent claims a device of a front-loadable syringe. However, the claims of the '669 and '261 patents describe the injector with some specificity.

- "a circular syringe receiving opening therein bounded by a circular annular periphery . . . " '261 patent, Claim 11

- "a circular syringe receiving opening bounded by a circular annular periphery . . . " '261 patent, Claim 30

(Doc. No. 30, Exhs. 1, 2). Clearly, this language describes a circular opening sized to accommodate the rear end of a syringe. Moreover, such a construction is supported by the ordinary dictionary definition of the terms. Webster's defines a "syringe" as "a device used to inject fluids into or withdraw them from the body or its cavities . . . " Webster's Third New International Dictionary at 2322 (1971). "Receive" is defined as "to take in: act as a receptacle or container for . . . ", and "opening" is defined as "something that is open: as a (1): BREACH, APERTURE . . . (2): an open width: SPREAD, SPAN . . . " *Id.* at 1580, 1894. Thus, the dictionary definition of a "syringe receiving opening" is an open width able to take in a device used to inject fluids into or withdraw them from the body. The language of the claims requires that this "open width" be circular.

The real issue dividing the parties is not the characteristics of a "syringe receiving opening" or "opening" but rather the location of such an opening. L-F, by asking the Court to conclude that the asserted claims involve an injector that does not require a pressure jacket, is asking the Court to conclude that the "syringe receiving opening" may be located anywhere, including the front-end of a pressure jacket.[9] Medrad argues, on the other hand, that

[9] Based on the language of Claim 19 of the '669 patent ("an opening at the front end of the injector), it appears, at the very least, such an opening would be somewhere on the front of the injector.

the injector described in the asserted claims requires a pressure jacket; therefore, the "syringe receiving opening" must be located at the front-end of the required pressure jacket.

The parties do not dispute that the asserted claims do not contain the term "pressure jacket". However, the absence of the term "pressure jacket" does not necessarily lead to the conclusion that the injector referred to in the asserted claims does not require a pressure jacket. While the claim language does not require a pressure jacket. While the claim language does not explicitly require a pressure jacket, neither does it explicitly describe a jacketless injector.[10] Because the claim language is ambiguous with respect to the requirement of a pressure jacket, the Court must conduct a review of all the intrinsic evidence (the claim language, the specification, and the prosecution history) to determine whether the injector described in the asserted claims requires a pressure jacket. *See Interactive Gift Express*, 256 F.3d at 1331.

Even the most cursory reading of the specification of the '669 and '261 patents[11] reveals that the injector described in the specification includes a pressure jacket:

> An animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is

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[10] At the time the patent applications for the '669 and '261 patent were filed, injectors that used disposable syringes included pressure jackets. (Doc. No. 57, Exh. 8 – Goethel Depo., p. 465, Exh. 9 – Fago Depo., p. 103, Exh.13, Dieterlen Depo., p. 141, Exh. 14 – Neer Depo, p. 135).

[11] As explained in detail in footnote 2, the '669 and '261 patents have the same specification.

> loadable and unloadable ***into and from the injector through the open front end of a pressure jacket of the injector*** . . .
> '669 patent and '261 patent, Abstract
>
> * * *
>
> It is an additional objective of the present invention to provide an injector wherein a used syringe can be removed and a new one ***inserted in the injector without retraction of the drive from the pressure jacket in most applications***. It is a further objective of the invention to allow for ***the removal of the used syringe from the jacket*** without disconnection of the injector tube from the syringe nozzle.
> '669 patent, col. 2, lines 32-39
> '261 patent, col. 2, lines 30-37

(Doc. No. 30, Exhs. 1, 2) (emphasis added). Not only does the specification contemplate an injector that includes a pressure jacket, a pressure jacket appears to be an essential component of the injector. According to the specification, the purpose of the pressure jacket is to reinforce the walls of the syringe used in the injector against pressures placed upon it by the injector:

> The syringe 32 is disposable, and includes walls which will withstand only moderate or low pressure. The walls are usually outwardly deformable under operating pressures, particularly pressures of 300 psi or more. Such higher pressures are necessary to overcome pressure drops through the injection tubing at higher flow rates, which are often desirable. ***The jacket 31 is made of a stronger transparent material that will withstand the operating pressures. When the syringe 32 is contained in the jacket 31, it is surrounded by the jacket 31***

> ***and supported by the jacket 31 against expansion caused by the fluid pressure within as the syringe 32 expands against the jacket wall.***
> '669 patent, col. 7, lines 15-26
> '261 patent, col. 7, lines 10-21
>
> * * *
>
> The pressure jacket 31 has a generally cylindrical inner bore . . . The bore 33 is dimensioned so as to receive through the remote end 35 the disposable syringe 32 and ***to support the syringe against expansion from fluid pressure within such fluid pressure may range to more than a thousand psi.***
> '669 patent, col. 7, lines 26-33
> '261 patent, col. 7, lines 22-29
>
> * * *
>
> To provide this front end loadable feature, the syringes of the preferred and illustrated embodiments of the present invention are provided with a front wall that is pressure restraining, that is, of sufficient strength to support the front of the syringe against the expected pressures within the syringe, and ***that is securable to the front end of the pressure jacket so as to complete the pressure restraining enclosure of the syringe within the pressure jacket and hold the syringe in the jacket.***
> '669 patent, col. 3, lines 1-9
> '261 patent, col. 2, lines 65-67 to col. 3, lines 1-7

(Doc. No. 30, Exhs. 1, 2) (emphasis added). Furthermore, the pressure jacket is an integral component of the injector described in the specifications. Other features of the injector, including the syringe used in the injector, rely on

the existence of a pressure jacket, and the specification does not describe how such features would work without the existence of a pressure jacket. (Doc. No. 30, Exh. 1, '669 patent: col. 2, lines 53-56; col. 3, lines 1-9; col. 7, lines 35-48; col. 8, lines 45-65; col. 9, lines 45-55; col. 10, lines 45-51). Quite simply, the specification fails to describe the components, design, or operation of an injector that does not include a pressure jacket.

In light of the specification, the fact that the asserted claims do not mention a pressure jacket simply does not support the conclusion that the asserted claims describe a jacketless injector. In *SciMed Life Systems*, 242 F.3d at 1341, the court concluded that:

> [w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.

In the present case, the opposite is true. The specification makes clear that the injector includes a pressure jacket. Accordingly, the Court concludes that the asserted claims do not cover a jacketless injector, even though the asserted claims might be considered broad enough to disclose a jacketless injector when read without reference to the specification. *See also, Watts*, 232 F.3d at 882-83 (claim that described pipe joints that could be "sealingly connected" limited to a misaligned taper angle connection method because specification discussed "the present invention" only in terms of the misaligned taper angle connection method); *Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1382 (Fed.Cir. 1999) (court limited a

computer system claim term ("frame") to character-based systems noting that the "only system that is described and enabled in the [patent] specification uses a character-based protocol" and that "references to other known protocols [did] not describe them as included in the applicant's invention, and that the specification would not be so understood by a person skilled in the field of the invention.").

Although L-F does not appear to disagree with the conclusion that the specification describes an injector that includes a pressure jacket, it maintains that a pressure jacket is not a required element of the injector described in the asserted claims. (Doc. No. 164, pp. 18-19). L-F argues that the specification of the '669 and '261 patents merely discloses a preferred embodiment of a front-loadable injector that includes a pressure jacket. (*Id.*). L-F points to the following excerpt, which appears immediately prior to the claims of the '669 and '261 patents:

> [t]he invention has been described in the context of its preferred embodiments. It will be appreciated by those skilled in the art that variations and alternatives to the embodiments described may be employed without departing from the principles of the present invention. Accordingly, this patent is not intended to be limited except by the scope of the following claims: . . .
> '669 patent, col. 13, lines 52-58
> '261 patent, col. 13, lines 54-60

(Doc. No. 30, Exhs. 1, 2). L-F correctly notes that a patent's claims are not limited to the preferred embodiment included in the specification, unless the language of the claims so limits them. *See Karlin Technology*, 177 F.3d at 973; *see also SRI Int'l*, 775 F.2d at 1122 (quoting *Smith v.*

Snow, 294 U.S. 1, 11 (1935)). Because the asserted claims do not mention a pressure jacket, L-F argues that the limitation of a pressure jacket cannot be read into the asserted claims of the '669 and '261 patents. (Doc. No. 164 at 18-19).

However, as Medrad correctly argues, a review of the specification reveals that every embodiment disclosed in the asserted patents requires a pressure jacket. An injector that includes a pressure jacket is not a preferred embodiment of the injector. As the following excerpt demonstrates, the only injector contemplated by the specification is an injector with a pressure jacket:

> According to the ***principles of the present invention***, there is provided an angiographic injector having a front end loadable syringe that can be ***loaded into and removed from the injector pressure jacket*** through an opening that is provided in the front end of the pressure jacket. To provide this front end loadable feature, the ***syringes of the preferred and illustrated embodiments of the present invention are provided with a front wall*** that is pressure restraining . . . and ***that is securable to the front end of the pressure jacket*** . . .
> '669 patent, col. 2, lines 64-67 to col. 3, lines 1-4
> '261 patent, col. 2, lines 61-67 to col. 3, line 1

(Doc. No. 30, Exhs. 1, 2) (emphasis added). Thus, a pressure jacket is a required element of the injector described in the asserted claims. *See Modine Mfg. Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed.Cir. 1996), *cert. denied, Showa Aluminum Corp. v. Modine Mfg.*, 518 U.S. 1005 (1996) ("[W]hen the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope

broader than that embodiment."); *Wang Labs*, 197 F.3d at 1382-83 (scope of claims limited to the only embodiment described in the specification).

The prosecution history also supports the conclusion that the asserted claims of the '669 and '261 patents involve an injector that requires a pressure jacket. The original applications which led to the '669 and '261 patents were filed on November 30, 1993 and April 6, 1995, respectively. (Doc. No. 57, Exhs. 23, 25). In the applications, all the independent claims included a pressure jacket and no dependent claims provided for the removal or elimination of the pressure jacket.

On September 12, 1994, L-F amended certain claims of the application that resulted in the '669 patent. (Doc. No. 57, Exh. 22). L-F removed the references to the pressure jacket in those claims. (*Id.*; Doc. No. 57, Exh. 2). Similarly, on April 6, 1995, L-F amended certain claims of the application that resulted in the '261 patent. (Doc. No. 57, Exh. 26). Again, L-F removed the references to the pressure jacket in those claims. (*Id.*; Doc. No. 57, Exh. 3). The specifications for the '669 and '261 patents remained the same.

It is undisputed that L-F amended the claims after it learned of Medrad's invention of a jacketless injector. Regarding the amendment of claims in light of a competitor's product, the Federal Circuit has held that:

> there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the

> applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course. . . .

Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed.Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989) (citing *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235 (Fed.Cir. 1985)). Thus, despite Medrad's argument to the contrary, L-F did nothing improper in amending the claims submitted in the original applications.

Although the fact that the original claims of the '669 and '261 patents were amended has no bearing on the Court's analysis, the substance of the original claims is relevant to its analysis. The original claims described an injector that required a pressure jacket. The specification was drafted for claims that disclosed an injector that required a pressure jacket, and this specification was not amended when the original claims were amended. It is unlikely that the specification, which was drafted for claims that included a pressure jacket, would describe an injector that does not require a pressure jacket, much less enable one skilled in the art to make and use such a device.

L-F argues that the prosecution history actually supports a conclusion that the injector described in the asserted claims does not require a pressure jacket. In an April 22, 1996, amendment to the '261 patent, L-F stated:

> In the claims as amended herein, the locking structure is not necessarily at the front end of the syringe, nor is there necessarily a pressure jacket . . .

(Doc. No. 84, Exh. 4(b), MED 000189). Based on this excerpt alone, L-F argues that "[t]he Patent Office Examiner understood that the claims of the '261 patent were directed to the syringe/injector locking structure either at the front or the rear of the syringe and with or without a pressure jacket." (Doc. No. 164, p. 20). This Court cannot accept such an argument. When faced with a similar argument in *DeMarini Sports*, 239 F.3d at 1326, the court held that "[d]rawing inferences of the meaning of claim terms from an examiner's silence is not a proper basis on which to construe a patent claim . . . " As in *DeMarini Sports*, it is L-F, not the Examiner, who commented on the absence of a pressure jacket. The Examiner did not comment either way on the existence of a pressure jacket.

Finally, L-F proposes that the doctrine of claim differentiation prevents the Court from interpreting the asserted claims as requiring pressure jackets. (Doc. No. 164, pp. 16-18). The doctrine of claim differentiation is based "on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Technology*, 177 F.3d at 971-72. However, courts cannot use the doctrine of claim differentiation to "broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." *Multiform Desiccants*, 133 F.3d at 1480. The doctrine of claim construction "only creates a presumption that each claim in a patent has a different scope; it is 'not a hard and fast rule of construction.'" *Kraft Foods*, 203 F.3d at 1368 (quoting *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed.Cir. 1998)); *Karlin Technology*, 177 F.3d at 972 (stating that the doctrine of claim differentiation is not a rigid rule).

According to L-F, the doctrine of claim differentiation precludes the Court from reading a pressure jacket requirement into claims 10 and 19 of the '669 Patent, as this requirement expressly appears in claim 14 which depends from claim 10.[12] (Doc. No. 164, p. 16-18). Likewise, L-F asserts that claim differentiation precludes the Court from reading a pressure jacket requirement into claims 1 and 18 of the '261 patent as this requirement expressly appears in dependent claims 2 and 19.[13] (*Id.*).

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[12] Claim 14 of the '669 patent provides as follows:

The method of claim 10 wherein:

the injector includes a hollow pressure jacket projecting therefrom having an open front end, the opening being located at the front end of the pressure jacket, the jacket having an internal cross-section dimensioned to surround and provide pressure restraining exterior support to the body of a syringe, inserted in the jacket through the opening, between at least the rearward end of the body to the rim;

the peripheral rim of the syringe is located at the forward end thereof;

the syringe inserting step includes the step of translating the syringe rearwardly and inserting thereby the body of the syringe, from the rearward end to the rim, into the jacket; and

the rotating step includes the step of locking the forward end of the syringe to the front end of the jacket.

[13] Claim 2 of the '261 patent provides as follows:

The disposable replacement syringe of claim 1 for use with an injector having a pressure jacket extending forwardly therefrom, the jacket having a cylindrical bore therein, the opening of the injector being the hollow bore of the jacket, and wherein the internal sections are fixedly located on the inside of the jacket, wherein:

the radially extending mating sections of the locking structure comprise mating sections positioned in a plane perpendicular to the axis of the body of the syringe so as to align with the internal sections on the jacket when the syringe is inserted in the jacket and to lock the syringe to the jacket.

(Continued on following page)

L-F is applying the doctrine of claim differentiation in an attempt to broaden the asserted claims beyond their scope determined in light of the specification. *See Multiform Desiccants*, 133 F.3d at 1480. The specification does not contemplate a jacketless injector or instruct on the concept, design, or use of a jacketless injector. Thus, the Court cannot conclude simply because the term "pressure jacket" was explicitly used in dependent claims and not in the asserted claims, that the patents disclose a jacketless injector. As stated above, claim differentiation only creates a presumption that each claim has a different scope. "[C]laims that are written in different words may ultimately cover substantially the same subject matter." *Multiform Sesiccants*, 133 F.3d at 1480; *see, also, Tandon Corp. v. U.S. Int'l Trade Comm.*, 831 F.2d 1017, 1023 (Fed.Cir. 1987) ("[P]ractice has long recognized that 'claims may be multiplied . . . to define the metes and bounds of the invention in a variety of different ways'.") (quoting *Bourns, Inc. v. United States*, 537 F.2d 486, 492 (Fed.Cir. 1976)).

Accordingly, the Court concludes that the terms "syringe receiving opening" and "opening" refer to a circular width of a size to accommodate the back end of a

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Claim 19 of the '261 patent provides as follows:

> The injector of claim 18 wherein:
>
> the injector has a pressure jacket extending forwardly from the housing, the jacket having a cylindrical bore therein, the syringe receiving opening of the injector being in the bore of the jacket; and
>
> the mating sections at the opening are fixedly located on the jacket, whereby the radially extending sections of the locking structure lock the syringe to the jacket.

(Doc. No. 30, Exhs. 1, 2).

syringe. Furthermore, the Court concludes that the injector described in the asserted claims of the '669 and '261 patent requires a pressure jacket and that the syringe receiving opening/opening is located at the front of this pressure jacket.

C. "High Pressure"

Next, the Court must interpret the term "high pressure" as it is used in Claim 10 of the '669 patent, which claims "[a] method of loading a tubular replacement syringe into a ***high pressure*** power injector for injecting fluid into an animal." (Doc. No. 30, Exh. 1; '669 patent, col. 10, lines 17-18) (emphasis added). As the following analysis demonstrates, the term "high pressure" must be construed in its context as an adjective of the term "power injector." Therefore, the Court will construe the entire term "high pressure power injector"

The language of Claim 10 does not define the term "high pressure." However, when describing the syringe to be loaded into the injector, the claim does state that the syringe must be "capable of withstanding, . . . an operating pressure of at least 100 psi [pounds per square inch]." (Doc. No. 30, Exh. 1; '669 patent, col. 10, lines 32-34). Based on this language, L-F argues that the term "high pressure" means operating at pressures of ***at least*** 100 psi. (Doc. No. 164, p. 20).

While the claim language relied on by L-F may be relevant to the Court's overall analysis of the term "high pressure", it cannot, standing alone, define the term "high pressure." The claim language does not clearly delineate the pressure range to be attributed to the term "high

pressure". As a result, the Court must interpret the claim language in light of the specification and prosecution history to ascertain the meaning of "high pressure."

When discussing injection pressures, the specification for the '669 patent states that:

> For applications such as the injection of contrasting fluid for CT scanning, pressure may typically be in the range of from 25 to 300 psi, while in some angiographic injection applications the pressure may range to 1200 psi or higher.
> '669 patent, col. 12, line 24-27

(Doc. No. 30, Exh. 1). In other words, an injector operates at a pressure range of 25-300 psi for CT applications and operates at a pressure range up to 1200 psi or higher for angiographic applications. Thus, by determining which applications the injector in Claim 10 is capable of performing, the Court can infer the meaning of "high pressure power injector" as it is used in Claim 10.

The claim language does not indicate whether the injector disclosed in Claim 10 is capable of CT applications, angiographic applications, or both CT and angiographic applications. Thus, the Court must look to the specification and prosecution history for guidance on this issue. The specification for the '669 patent indicates that the injector described in the specification can be used for angiographic and/or CT applications:

> FIG. 1 is a perspective view of an angiographic CT injector embodying principles of the present invention. '669 patent, col. 5, lines 21-22

* * *

> Referring to FIG. 1, an angiographic injector 10 according to another preferred embodiment of the present invention is illustrated, configured for CT applications. '669 patent, col. 6, lines 12-14

(Doc. No. 30, Exh. 1). The question then becomes whether the injector described in Claim 10, like the injector described in the specification, is capable of both CT and angiographic application, only CT applications, or only angiographic applications.

The specification goes on to state that the fluid used in the injector "may be of relatively high pressure in the range, usually over 200 psi." (Doc. No. 30, Exh. 1; '669 patent, col. 12, lines 22-23). The implication of this statement is that pressures over 200 psi are considered high, therefore a "high pressure power injector", as in Claim 10, would be an injector that operates at pressures of 200 psi or higher, which would include both CT applications and angiographic applicaitons.

The conclusion that "high pressure power injector" refers to an injector that is capable of performing both CT and angiographic applications is also supported by the prosecution history of the '669 patent. L-F offered the following statements to the PTO Examiner during prosecution of the '669 patent:

> Claim 95[14] relates specifically to ***high pressure power injectors, as for example the injectors used in angiography, with CAT[15] equipment and the like.*** For such uses, applicants' front

[14] Claim 95 issued as claim 10 of the '669 patent.

[15] The terms CT and CAT are synonymous.

> loading injector is totally new. The front loading feature is embodied in the simple operator motion of inserting the syringe into the injector by a rearward axial motion and twisting the syringe a fraction of a turn (as for example the quarter turn of the embodiment described in the specification).

(Doc. No. 84, Exh. 3 (B) at MED 002326). (emphasis added). At first glance, it is unclear whether "with CAT equipment and the like" is a phrase modifying the term angiography or whether it is part of a series of injector applications with "angiography" being the first in the series, with "with CAT equipment" being the second in the series, and with "the like" being the third in the series. However, a reading of the full prosecution history reveals that this statement, although grammatically incorrect, involves a series of injector applications.[16] Therefore, Claim 95 related to "high pressure power injectors" such as those used in angiography and those used with CT equipment.

It should be noted that the individual independent claims of the '669 patent refer to an injector as a "high pressure power injector", a "power injector", or simply an

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[16] When discussing Claim 91 (issued as claim 1 of the '669 patent), L-F states that "claim 91 relates to the advantage of the present invention by which the efficiency of the use of a power injector, ***such as used in angiography and with CAT scanning equipment***, is enhanced." When distinguishing this "present invention" from prior art devices, L-F states that "[t]he prior art devices provided for angiography and CAT scan uses do not have this capability." From these statements, the Court infers that "used . . . with CAT scanning equipment" is the equivalent of "CAT scan uses". (Doc. No. 84, Exhibit 3 (B) at MED 002324-002325) (emphasis added).

"injector."[17] Nothing in the language of the various claims indicates whether the use of these different terms is intended to describe injectors capable of different applications. Medrad would argue that the use of these different terms indicates that the injector is intended to perform different applications. However, there is nothing in the specifications or prosecution history to support this conclusion. In fact, the prosecution history supports the opposite conclusion, that there is no difference in the terms. During patent prosecution, L-F stated the following to the PTO Examiner:

> Applicants' invention relates to relatively ***high pressure power injectors*** . . . In order to focus more clearly on the particular features of the present invention and the advantages it provides, applicants have replaced the claims with seven independent claims, each relating to a particular unique problem and unique advantageous solution provided by the invention.

(Doc. No. 84, Exhibit 3(B) at MED 002324) (emphasis added). L-F then went on to discuss the seven independent claims referred to in this excerpt, which were apparently related to "high pressure power injectors." Those claims, 91, 93, 95, 100, 101, 103, and 105, issued as independent claims 1, 6, 10, 19, 20, 22, and 24 respectively. The issued claims refer to an injector as a "power injector" (claims 1, 19, 22), a "high power pressure injector" (claims 10, 20, 24), and an "injector" (claim 6). The inference to be drawn is that the terms "power injector", "high power pressure

[17] The independent claims of the '669 patent are 1, 6, 10, 19, 20, 22, 24, 31, and 36.

injector", and "injector" all refer to the same type of injector, i.e., a "high pressure power injector." This conclusion is consistent with the principle that "[c]laims that are written in differnet words may ultimately cover substantially the same subject matter." *Multiform Desiccants*, 133 F.3d at 1480

Accordingly, based on all the intrinsic evidence, the Court concludes that the "high power pressure injector" described in Claim 10 of the '669 patent is capable of performing angiographic as well as CT applications. As such, it operates at pressures ranging from 25 psi to in excess of 1200 psi.

D. "Physical Indicia"

L-F moves the Court to construe the term "physical indicia" as it is used in the asserted claims of "the '612 patent" and the '197 patent.[18]

Each of the asserted independent claims of the '612 patent and the '197 patent includes the term "physical indicia."[19] These "physical indicia" relate to various

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[18] The asserted claims of the '612 patent are 7, 8, 10, and 11 and the asserted claims of the '197 patent are 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, and 27.

[19] . . . a detector located proximate to a syringe . . . for detecting a physical indicia on said syringe related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia,
'612 patent, Claim 7,

detecting a physical indicia on a syringe . . . , said indicia being related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia . . .
'612 patent, Claim 10

(Continued on following page)

. . . a syringe having . . . physical indicia related to the distance of the plunger from an end of said syringe . . .
'197 patent, Claim 1

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to the distance of the plunger from an end of said syringe . . .
'197 patent, Claim 4

. . . a syringe having . . . physical indicia related to the amount of fluid in the syringe . . .
'197 patent, Claim 7

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to amount of fluid in said syringe . . .
'197 patent, Claim 10

. . . a syringe having . . . physical indicia related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector . . .
'197 patent, Claim 13

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to the end of travel position of a ram moved by said motor when said syringe is mounted to the injector . . .
'197 patent, Claim 16

. . . a syringe having . . . physical indicia related to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector . . .
'197 patent, Claim 19

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to the range of travel of a ram moved by said motor when said syringe is mounted to the injector . . .
'197 patent, Claim 22

. . . wherein the control circuit is operable obtain an offset value from physical indicia detected on the syringe . . .
'197 patent, Claim 25

. . . detecting a physical indicia on a syringe . . . , said indicia being related to the capacity of said syringe, to obtain an offset value, computing a value indicative of the location of said plunger within said syringe by applying the store offset value to the tracked location of said motor, and

(Continued on following page)

properties of a syringe such as the capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, and an offset value.

L-F urges this Court to give the term "physical indicia" its ordinary and customary meaning without looking beyond the claim language. Physical is defined as "of or relating to . . . material things as opposed to things mental, moral, spiritual, or imaginary." Webster's Third New International Dictionary at 1706 (1971). Indicia is defined as "a distinctive mark that indicates or that is felt to indicate the nature or quality or existence or reality of something." *Id.* at 1150. Thus, the term "physical indicia" means a tangible marking on a syringe that relates to a specific property of the syringe. L-F proposes that these specific properties include the capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, and an offset value that is related to the capacity of a syringe. (Doc. No. 164, p. 24).

Medrad does not appear to disagree that the term "physical indicia" means a tangible marking on a syringe that relates to a specific property of the syringe. Rather, Medrad is arguing that "physical indicia", as used in the '612 and '197 patents, is limited only to indicia that

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ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.
'197 patent, Claim 27
(Doc. No. 30, Exhs. 3, 4).

indicate the length of an extender element used in a syringe.[20] (Doc. No. 172, pp. 29-30).

It should be noted that the language of the asserted claims does not limit the term "physical indicia" to the use of an extender element. Rather, the claim language unambiguously states that "physical indicia" are related to capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, and an offset value. *Supra*, fn. 19. Therefore, unlike the ambiguous language construed in Section III(B) ("syringe receiving opening"/requirement of a pressure jacket), the claim language relating to the term "physical indicia" is clear and unambiguous. This distinction is significant because it affects the manner in which this Court will view the rest of the intrinsic evidence, *i.e.*, the specification and the prosecution history. The Federal Circuit has recently held that:

> If the claim language is clear on its face, then our consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified. A deviation may be necessary if "a patentee [has chosen] to be his own lexicographer and use terms in manner other than their ordinary meaning." *Vitronics*, 90 F.3d at 1582, 39 USPQ2d at 1576. A deviation may also be necessary if a patentee has "relinquished [a] potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference." *Elkay Mfg.*

[20] An extender is an element in a syringe that compensates for variations in the location of the plunger in pre-filled syringes to accommodate varying syringe volumes.

> *Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979, 52 USPQ2d 1109, 1113 (Fed. Cir. 1999). If however the claim language is not clear on its face, then our consideration of the rest of the intrinsic evidence is directed to resolving, if possible, the lack of clarity.

Interactive Gift Express, 256 F.3d at 1331. Therefore, when construing the term "physical indicia", the Court will rely on the rest of the intrinsic evidence to determine only if a deviation from the clear language of the claim is specified rather than to resolve the meaning of the claim language, as it did in Section III(B).

Medrad bases its argument that "physical indicia" is limited to indicating the length of an extender on the following excerpts from the specifications of the '612 and '197 patents[21]:

> The offset value . . . may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.
> '612 patent, Abstract

> Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.
> '612 patent, col. 4, lines 2-3
> '197 patent, col. 4, lines 1-2[22]

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[21] As explained in detail in footnote 4, the '612 and '197 patents have the same specification.

[22] Medrad also cites to unasserted Claim 3 of the '612 patents which states, in pertinent part, that the injector contains a detector used for "detecting the length of the extender which is attached to said

(Continued on following page)

(Doc. No. 30, Exhs. 2, 3). Medrad argues that this language defines "physical indicia" as indicia related only to length of extender. Not surprisingly, L-F counters that this language is merely a preferred embodiment in which the physical indicia on the syringe indicates a specific property – the length of an extender.[23] (Doc. No. 182, p. 15). L-F argues that this embodiment does not preclude the use of physical indicia in relation to other properties of the syringe (*i.e.*, capacity, distance of the plunger from the end, amount of fluid, etc.).

Medrad also cites to the prosecution history of the '197 patent to support its interpretation. (Doc. No. 172, pp. 30-32). Claim 7 of the '197 patent includes the element "physical indicia related to the amount of fluid in the syringe," and claim 10 of the '197 patent includes the element of a "[physical] indicia being related to amount of fluid in said syringe." During the prosecution of the '197 patent, the PTO Examiner rejected L-F's proposed claims 7 and 10 due to failure to comply with the written description requirement of 35 U.S.C. section 112. In the Detailed Action, the PTO Examiner, in rejecting claims 22-45, explained that

> The specification, as originally filed on 28 August 1997, does not adequately support the

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plunger from physical indicia on the syringe or extender and generating an electrical signal representative of the detected length . . . " (Doc. 30, Exh. 3). In light of the law of claim differentiation discussed in section III(B), this claim language does not support Medrad's argument. Unlike the siguation in section III(B), L-F is not attempting to broaden the asserted claims beyond the scope of the claim language.

[23] The Court notes that the language in question falls under the heading "Summary of the Invention" as opposed to the later heading of "Description of the Preferred Embodiments."

> embodiments set forth in claims 22-27 wherein the syringe includes physical indicia related to the position of the plunger; claims 28-33 wherein the syringe includes physical indicia related to the amount of fluid in the syringe; claims 34-39 wherein the syringe includes physical indicia related to the end of travel position of a ram moved by the motor; and claims 40-45 wherein the syringe includes physical indicia related to the range of travel of a ram moved by the motor. The only recitation in the specification regarding the indicia on the syringe is on page 6, lines 23-26:
>
> 'Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.'
>
> Thus there is inadequate disclosure of such indicia being related to plunger position, fluid quantity, end of travel position of the ram, and range of travel of the ram as now claimed. The disclosure only provides support for the indicia being related to the length of the extender.

(Doc. No. 172, Exh. 10, p. 2). The PTO Examiner rejected claims 22-45 based on failure to comply with 35 U.S.C. section 112, first paragraph. (*Id.* at 3).

In response to the PTO Examiner, L-F argued that the other elements of "capacity of the syringe" and "amount of fluid in the syringe" were related to the length of the extender, and thus, those elements were supported in the specification through the references to the length of the extender:

> With respect to claims 28-33, the Examiner submits that the specification does not support physical indicia on a syringe related to the

> amount of fluid in the syringe, and does not support computing the amount of fluid in the syringe.
>
> In response, Applicant would note that a comparison of Fig. 1A to Fig. 1B clearly shows that the capacity of a syringe having an extender is less than the capacity of a syringe that does not have such an extender. Notably, the syringe shown in Fig. 1B is a 'pre-filled' syringe, thus the syringe is filled to its capacity when it is installed on the injector. Since the capacity of the syringe is directly related to the length of the extender in the syringe, it follows that the amount of fluid in the syringe is directly related to the length of the extender. Accordingly, the indicia recited at page 6, which indicates the length of the extender, also thereby indicates the amount of fluid in the syringe. Indeed, at page 4, line 4 it is stated that the extender 'reduc[es] the initial volume of the pre-filled syringe'. Accordingly, Applicant submits that the specification clearly describes a syringe having indicia related to the amount of fluid in the syringe.

(*Id.* at 12-13). L-F made similar arguments with respect to physical indicia relating to the distance of the plunger from the end of a syringe, the end of travel position of an injector ram, and the range of travel of an injector ram. (*Id.* at 10-12, 13-16). The patent was subsequently issued by the PTO without any substantive amendment by L-F of the claims or specification. (Doc. No. 174, Exh. 4, Notice of Allowance on 4/1/99, p. 139).

The Court would agree with Medrad's argument that the term "physical indicia" is limited to indicia related to the length of the extender if the preceding excerpts from L-F's response to the PTO Examiner reflected the entirety

of L-F's response. However, in the final paragraph of L-F's response, L-F stated that:

> Applicant would further note that although the supporting specific embodiment of the invention found in the specification is disclosed in the context of compensating for the presence of a plunger extender attached to the plunger, the independent claims do not necessarily require a plunger extender, but rather are directed generally to using information from indicia on a syringe to compensate for syringes having differing initial plunger positions, differing initial amounts of fluid, differing end-of-travel positions or ranges of travel for the ram.

(*Id.* at 16). Thus, L-F unequivocally stated to the PTO Examiner that the asserted claims of the '197 patent were not limited to indicia relating to the length of an extender.

In order to narrow unambiguous claim language based on the prosecution history, an accused infringer must "demonstrate that the patentee 'defined' the claim as 'excluding' a broader interpretation 'with reasonable clarity and deliberateness.'" *Pall Corporation v. PTI Technologies, Inc.*, 259 F.3d 1383, 1392-93 (Fed. Cir. 2001) (quoting *Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1294-95 (Fed.Cir. 2000)). Based on the final paragraph of L-F's response, the Court cannot conclude that L-F limited the asserted claims to "physical indicia" only related to the length of an extender. L-F clearly viewed "physical indicia" as encompassing other syringe characteristics besides the length of the extender.

Thus, the Court construes the term "physical indicia" as a tangible mark on a syringe relating to various properties of the syringe. The properties may include the capacity

of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value.

Medrad argues that in the event the Court accepts L-F's construction of the term "physical indicia", the '612 and '197 patents are invalid pursuant to 35 U.S.C. § 112 for lack of enablement and failure to provide an adequate written description. (Doc. No. 172, pp. 32-33). This argument will be addressed in section VII(A).

E. "Motor" and "Tracks the Location of Said Motor"[24]

L-F requests that the Court interpret the terms "motor" and "tracks the location of said motor" as they are used in the '612 and '197 patents. Each of the asserted independent claims of the '612 and '197 patents recites that the injector has a motor which advances and retracts a plunger and that the device includes a control circuit which causes the motor to move and tracks the location of the motor while moving the motor.

L-F asserts that "motor" actually means the "drive mechanism" and "tracks the location of said motor" means "tracks the location of the drive mechanism." (Doc. No. 164, pp. 26-27). Medrad, relying strictly on dictionary definitions, argues that "motor" means a machine that

[24] The Court reviewed L-F's Supplementation in Reply (Doc. No. 220) relating to this issue, Medrad's Motion to Strike L-F's Supplementation (Doc. No. 224), and L-F's memorandum in opposition (Doc. No. 235). These filings relate to extrinsic evidence not considered by the Court when construing the claim terms.

imparts motion and that "tracks the location of said motor" means that the motor is moving to another location within the injector and that this movement is being tracked. (Doc. No. 172, pp. 33-34). The Court finds both L-F's and Medrad's arguments illogical and unpersuasive.

The terms "motor" and "tracks the location of said motor" are not defined by any of the asserted claims in the '612 and '197 patents. Therefore, the claims must be read in light of the specification to define the terms. *See Interactive Gift Express*, 256 F.3d at 1331.

The Court believes the following excerpt from the specification sufficiently defines the terms in question.

> The motor 98 is coupled to a gear box which translates rotary motion of the motor to linear translation of the plunger . . . The rotation of the motor is detected by optical encoder 166 . . . Encoder 166 sends electrical pulses to circuit board 160, which relays them to PowerPC 50, allowing CPU 52 on the PowerPC to monitor movement of the motor.
> '612 patent, col. 10, lines 50-62
> '197 patent, col. 10, lines 48-60

(Doc. No. 30, Exhs. 3, 4). In other words, the "motor" is a mechanism that rotates and this rotation causes gears in the gear box to move which ultimately results in the linear movement of the plunger. "Track the location of said motor" refers to the monitoring of the rotation of the motor.[25]

[25] In Plaintiff Liebel-Flarsheim Company's Opposition to Medrad's Motion for Partial Summary Judgment of Invalidity and Non-Infringement of the Asserted Claims of U.S. patent Nos. 5,662,612 and

(Continued on following page)

L-F's proposed interpretation equates "motor" with the "drive mechanism of the plunger". However, the term "motor" is shown in the specifications and used in the claims as a distinct element. "Motor" is assigned reference number 98 and is depicted in Figure 5 of both patents, where the motor is different and distinct from the "gear box" (Ref. No. 164), the "optical encoder" (Ref. No. 166), the "plunger" (Ref. No. 12), the "linear pot" (Ref. No. 168), the "main circuit board" (No. 160), and other elements. (Doc. No. 30, Exhs. 3, 4). It appears that the "drive mechanism" includes parts in addition to the motor such as the gearbox, the ram, and all of the component parts that work to drive the plunger. Therefore, the motor cannot be the equivalent of the drive mechanism of the plunger.

Medrad's proposed interpretation, that the motor is moving from location to location, ignores the specification which clearly indicates that the motor is stationary. Furthermore, Medrad's proposed interpretation would exclude the preferred embodiment disclosed in the '612 and '197 patents, which describes a motor that is stationary. *See Vitronics*, 90 F.3d at 1583; *Burke, Inc. v. Brundo Independent Living Aids, Inc.*, 183 F.3d 1334, 1341 (Fed.Cir. 1999).

In light of the clear and unambiguous language of the specification, the Court finds that its construction of the terms "motor" and "tracking the movement of the motor" is

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5,928,197 (Doc. 174), L-F, in its argument regarding the construction of the terms "motor" and "tracks location of said motor", presented an argument identical to the Court's present analysis of these terms. It is unclear why L-F presented a completely different, and in the Court's opinion incorrect, argument in its summary judgment motion for claim construction.

the more logical construction. Therefore, the Court construes the term "motor" as a stationary mechanism that rotates causing the movement of the gears in the gearbox and the term "tracking the movement of the motor" as the monitoring of the rotation of the motor.

IV. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY FOR LACK OF ENABLEMENT OF THE ASSERTED CLAIMS OF THE '669 AND '261 PATENTS (DOC. 168)

Medrad failed this motion for partial summary judgment. (Doc. No. 168). L-F filed a Response (Doc. No. 175) to which Medrad filed a Reply (Doc. No. 187).

Based on the Court's construction that a pressure jacket is a required element of the asserted claims of the '669 and '261 patents (Section III(B)), the Court declares **MOOT** Defendant's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the Asserted Claims of the '669 and '261 Patents (Doc. No. 168).

V. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY AND NON-INFRINGEMENT OF THE ASSERTED CLAIMS OF THE '669 AND '261 PATENTS (DOC. 57)

Medrad filed this motion for partial summary judgment. (Doc. No. 57). L-F filed a Response (Doc. No. 84) to which Medrad filed a Reply (Doc. No. 99).[26] [27]

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[26] The Court also reviewed Medrad's Motion to File a Sur-Reply (Doc. No. 190) and L-F's memorandum in opposition (Doc. No. 196).

[27] L-F also filed a motion to file a sur-reply (Doc. No. 104). Medrad filed a memorandum in opposition (Doc. No. 113) to which L-F filed a

(Continued on following page)

A. Brief Background

Medrad seeks summary judgment arguing that if the asserted claims of the '669 and '261 patents are construed as not requiring a pressure jacket, the patents are invalid for failure to comply with the written description requirements of 35 U.S.C. § 112, ¶ 1. In the alternative, Medrad argues that if the asserted claims are construed as requiring a pressure jacket, it is entitled to summary judgment for non-infringement of the '669 and '261 patents because the accused products do not include a pressure jacket.

Based on the Court's construction that the asserted claims require a pressure jacket (Section III(B)), the portion of Medrad's motion for summary judgement based on invalidity is **MOOT**. The Court now addresses Medrad's non-infringement portion of its motion.

B. Non-Infringement of the '669 and '261 Patents

Infringement is the unlicenced making, using, or selling of a patentee's claimed invention. 35 U.S.C.A. § 271(a). Literal infringement occurs when the accused product is precisely described in a patent claim. *SRI Int'l*, 775 F.2d at 1123. Under the doctrine of equivalents, infringement occurs when the accused product "performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same

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Reply (Doc. No. 120). L-F did not file a sure reply but instead filed a supplemental memorandum in opposition (Doc. No. 195). Medrad filed a Response (Doc. No. 199) to which L-F filed a Reply (Doc. No. 203). These filings involve findings by the European Patent Office. This Court did not consider these findings when ruling on this matter.

overall result as the claimed invention." *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed.Cir. 1987) (en banc), *cert. denied*, 485 U.S. 961, 485 U.S. 1009 (1988).

To determine infringement, the court must apply a two-step analytic procedure. *Wang Labs.*, 197 F.3d 1377, 1380-81 (Fed.Cir. 1999) (citations omitted); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1476 (Fed.Cir. 1998) (citation omitted). First, the court must construe the scope and meaning of the patent claims asserted, which are questions of law. *Id.* Then, the court must apply those claims to the allegedly infringing device or process, which is a question of fact. *Id.*

To establish literal infringement, every limitation set forth in a claim must be found in the accused product, exactly. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed.Cir. 1999), *cert. denied*, 529 U.S. 1066 (2000) (quoting *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed.Cir. 1998)); *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed.Cir. 1995), *cert. denied*, 514 U.S. 987 (1995). As a matter of law, there is no literal infringement if any claim limitation is absent from the accused device. *Elkay Mfg. Co.*, 192 F.3d at 980.

Because "infringement is itself a fact issue, a district court must approach a motion for summary judgment of infringement or non-infringement with a care proportioned to the likelihood of its being inappropriate." *SRI Int'l*, 775 F.2d at 1116 (citing *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1573 (Fed.Cir. 1985)); *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 974 (Fed.Cir. 1985). "[A] trial often establishes facts and inferences not gleanable from papers submitted pre-trial." *SRI Int'l*, 775 F.2d at 1116.

In section III(B), this Court held that the injector described in the asserted claims of the '669 and '261 patents required a pressure jacket. It is undisputed that the accused injectors do not include a pressure jacket. Therefore, because a claim limitation, a pressure jacket, is absent from the accused products, there is no literal infringement of the '669 and '261 patents as a matter of law. *Mas-Hamilton Group*, 156 F.3d at 1211 (Fed.Cir. 1998) ("If even one limitation is missing or not met as claimed, there is no literal infringement.") (citations omitted).

Furthermore, it does not appear, nor has L-F argued, that the accused products include the equivalent of a pressure jacket. Therefore, there is no infringement under the doctrine of equivalents. *See Mas-Hamilton Group*, 156 F.3d at 1215-16 (explaining that when an accused device is missing the equivalent of a claim limitation there is no infringement under the doctrine of equivalents). *See also, Anderson*, 477 U.S. at 248 (The non-moving party "'may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.'" (citations omitted)).

Thus, the Court concludes that there is no genuine issue as to any material fact with respect to non-infringement of the '669 and '261 patents and that Medrad is entitled to judgment as a matter of law.

Thus, the Court **GRANTS**, with respect to non-infringement, Defendant's Motion for Partial Summary Judgment of Invalidity and Non-infringement of the Asserted Claims of the '669 and '261 Patents (Doc. 57) and declares the motion **MOOT** with respect to invalidity.

VI. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE '612 AND '197 PATENTS BECAUSE DEFENDANT PRACTICES ITS OWN PATENT WHICH IS PRIOR ART TO THE ASSERTED PATENTS (DOC. 162)

Medrad filed this motion for partial summary judgment. (Doc. No. 162). L-F filed a Response (Doc. No. 163) to which Medrad filed a Reply (Doc. No. 170).[28]

A. Brief Background

Medrad seeks summary judgment on L-F's claims that Medrad infringed claims 7, 8, 10, and 11 of the '612 patent and claims, 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, and 27 of the '197 patent.

The '612 patent issued on September 2, 1997 from an application filed June 26, 1995, and the '197 patent issued on July 27, 1999 from an application filed August 28, 1997. (Doc. No. 162, Exhs. 1, 2). The claims of the '197 and '612 patents recite specific uses of encoding information on a syringe which the patents refer to as "physical indicia."[29]

Prior to the filing of L-F's above-mentioned applications, Medrad, on August 17, 1992, filed an application which resulted in U.S. Patent No. 5,383,858 ("the '858 patent"). (Doc. No. 162, Ex. 3). The '858 patent, entitled "Front-Loading Medical Injector and Syringe For Use Therewith," was issued on January 24, 1995. Among other

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[28] The Court also reviewed L-F's Motion to File a Sur-Reply (Doc. No. 178), Medrad's memorandum in opposition (Doc. No. 180), and L-F's reply (Doc. No. 188).

[29] *Supra*, fn. 19.

things, the '858 patent discloses a method and device for syringe encoding (collectively "syringe encoding").[30]

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[30] The '858 patent provides as follows:

> With further reference to FIG. 2, a system 67 for transmitting syringe information from the syringe 22 to an injector controller 68, illustrated in phantom lines in FIG. 1, while attaching the syringe to the injector housing front wall mounting assembly 23, also is provided. In this instance, the system 67 comprises an encoding device 70, such as a bar code having spaced bars 70b and located on the syringe 22, and a sensor 72 located on the injector 27, as for example, in a second one of the connector assembly retaining flanges 23f. Then, as the syringe 22 is rotated into its mounted position, the sensor 72 reads the encoding device 70 and forwards associated signals to the injector controller 68, which then interprets the signals and modifies the function of the injector apparatus 20 accordingly. Examples of the information which could be encoded on the encoding device 70 include dimensions of the syringe 22, content of the syringe in the case of a pre-filled syringe, manufacturing information such as lot numbers, dates and tool cavity number, recommended contrast media flow rates and pressures, and loading/injection sequences. As an alternative to the encoding device 70 being a bar code with spaced bars 70b, the encoding device also could include raised surfaces 70s corresponding to the spaced bars, which then would be read by a suitable injector sensor 72 in a similar manner, as the syringe 22 is mounted on the injector housing front wall 24. In addition to the encoding device 70, one may also use mechanically readable devices, e.g., a slot, hole, or projection on the syringe 22 or plunger 38 to register against a switch on the mounting assembly 23, or alternatively an optically readable device, e.g. characters, dots and other geometric shapes, that will send information concerning the type of syringe used to the intelligent circuits of the injector. '858 patent, col. 6, lines 31-65

(Doc. No. 162, Exh. 3).

B. Discussion

On summary judgment, Medrad argues that the accused products cannot, as a matter of law, infringe the '612 and '197 patents because Medrad practices its own prior art patent, the '858 patent. (Doc. No. 162, p. 10). Medrad contends that the accused products include the syringe encoding covered by the '858 patent. (Doc. No. 162, p. 2). Medrad argues further that because the '858 patent was issued in 1995, it constitutes prior art to the '612 and '197 patents, which were issued in 1997 and 1999, respectively. (Doc. No. 162, p. 3). Therefore, Medrad contends that it is practicing the prior art. If Medrad's conclusion is correct, the accused products cannot infringe the asserted patents literally or under the doctrine of equivalents. *See Fiskers, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1323 (Fed.Cir. 2000), *cert. denied*, 121 S.Ct. 1603 (2001) (it is an affirmative defense of an alleged infringer to establish that it is practicing the prior art).

To determine whether Medrad is practicing the prior art the Court must determine (1) whether the '858 patent is prior art to the '612 and '197 patents and (2) whether the accused products are covered by the '858 patent with respect to syringe encoding.

The parties appear to agree that the '858 patent is prior art to the '612 and '197 patents. Therefore, the next issue for the Court's consideration is whether the accused products are covered by the '858 patent, in particular with respect to the patent's syringe encoding disclosures. Medrad contends that the accused products include the syringe encoding disclosed by the '858 patent. In support of its contention, Medrad relies on the Second Declaration of Joseph B. Havrilla, the Senior Vice President of New

Project Development for Medrad. (Doc. No. 162, Exh. 6). In his declaration, Havrilla states that:

> 3. Medrad's Envision CT™ and Medrad Vistron CT® injectors, and the syringes for use with these injectors, incorporate and practice inventions described in Medrad U.S. Patent No. 5,383,858 ("the '858 patent") filed August 17, 1992 and issued January 24, 1995.
>
> 4. In particular, Medrad's Envision CT™ and Medrad Vistron CT® injectors, and the syringes for use with these injectors, feature a syringe encoding apparatus and method as disclosed in column 6, lines 31-65 of the Medrad '858 patent. The same disclosure of syringe encoding appears in two other Medrad patents, U.S. Patent Nos. 5,997,502 ("the '502 patent") and 6,090,064 ("the '064 patent"), both of which have an August 17, 1992 effective filing date and both of which also explicitly claim syringe encoding. Medrad's Envision CT™ and Medrad Vistron CT® Injectors, in particular the syringe encoding aspects of these injectors, operate as disclosed in Medrad's '858 patent and as claimed in Medrad's '502 and '064 patents.

(Doc. No. 162, Exh. 6, ¶¶ 3, 4). Medrad also cites to statements made by two of L-F's own experts, Dennis A. Guenther and Arthur J. Helmicki, in support of its argument.[31] With respect to the statements of Guenther and

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[31] Medrad cited to the January 31, 2001 *Rebuttal report of Dennis A. Guenther, Ph.D., P.E. Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure* in Civil Action C 1-98-858, (Doc. 162, Exh. 8) and to the Report of Arthur J. Helmicki, Ph.D., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, (Doc. 162, Exh 9 (page 1 of Exh. B and page 1 of Exh. C)).

Helmicki, the Court concludes that they are not related to the issue of whether the accused products include the syringe encoding disclosed in the '858 patent. Therefore, the only credible evidence Medrad has presented that the accused products are covered by the '858 patent with respect to syringe encoding is the declaration of Havrilla.

L-F does not take a position on whether the accused products practice the prior art of the '858 patent with respect to syringe encoding. Rather, L-F argues that this issue is irrelevant because even if the accused products practice the prior art of the '858 patent, they ***also*** practice the subject matter of the claims of the '612 and '197 patents, which, L-F contends, are improvement patents of the '858 patent.[32] (Doc. No. 163, pp. 8-10). As L-F accurately states, when a patentee claims an improvement over a prior invention, other parties may practice variations of that prior invention, as long as the variations are not the same as, or an equivalent of, the improvement claimed by the patentee. *See Thomas & Betts Corp. v. Litton Systems, Inc.*, 720 F.2d 1572, 1580 (Fed.Cir. 1983) (citing *Sealed Air Corp. v. U.S. International Trade Comm'n*, 645 F.2d 976, 984-85 (C.C.P.A. 1981).

L-F argues that while the '858 patent discusses syringe encoding, it only refers to syringe encoding applications not claimed in the '612 and '197 patents. According to L-F, the syringe encoding disclosed in the '858 patent identifies:

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[32] Medrad has not disputed L-F's argument that the '612 and '197 patents are improvement patents of the '858 patent.

- dimensions of the syringe
- content of the syringe in the case of a pre-filled syringe
- manufacturing information such as lot numbers, dates and tool cavity number
- recommended contrast media flow rates and pressures
- loading/injections sequences

(Doc. No. 163, p. 6 (citing '858 patent, col. 6, lines 45-51)). On the other hand, L-F points out that the syringe encoding of the '612 and '197 identifies:

- capacity of the syringe
- distance of the plunger from an end of the syringe when the syringe is initially installed on the injector
- amount of fluid in the syringe
- end of travel position of an injector ram coupled to the plunger when the syringe is coupled to the an injector
- range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector

(Doc. No. 163, pp. 4-5 (citing Exh. 1, Helmicki Affidavit ¶ 7)).[33] Further, according to L-F, the '858 patent fails to address the use of syringes that have "different end-of-travel

[33] In its reply (Doc. No. 170), Medrad asks this Court to strike Helmicki's declaration as being not credible. The Court finds Medrad's argument on this issue unpersuasive and declines to strike Helmicki's declaration.

positions, capacities, or different amounts of fluid or plunger-end-of-syringe distances." (Doc. No. 163, p. 7). Thus, L-F argues that the '858 patent "does not disclose the uses for indicia that are recited in the '612 and '197 patent claims." (Doc. No. 167, p 8). L-F argues that the accused products include syringe encoding that identifies the information contained in the '612 and '197 patents. (Doc. No. 167, p 10).

Medrad, relying on its claim construction argument that the term "physical indicia" is only related to the length of the extender, does not address L-F's argument that the accused products include syringe encoding that identifies other information besides the length of an extender. In section III(D), this Court rejected Medrad's proposed construction. Therefore, by relying exclusively on its proposed claim construction, which the Court had concluded is incorrect, Medrad has failed to present any factual evidence to dispute L-F's argument that the accused products include syringe encoding that identifies the information contained in the '612 and '197 patents.

However, the Court recognizes the difficulties faced by the parties due to the sequencing of motions in this matter. Therefore, the Court invites the parties to rebrief this argument in light of the Court's construction of the term "physical indicia". ***However, neither party should revisit the claim construction issue in any such briefings***. Briefings should be confined to the issue of infringement in light of this Court's construction of the term "physical indicia" in section III(D). Defendant Medrad's revised motion is due on November 19, 2001, Plaintiff L-F's response is due on December 10, 2001, and Defendant Medrad's reply is due on December 31, 2001.

Accordingly, the Court **RESERVES JUDGMENT** on Medrad's Motion for Partial Summary Judgment of Non-infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which Is Prior Art to the Asserted Patents (Doc. 162).

VII. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY OF THE ASSERTED CLAIMS OF THE '612 AND '197 PATENTS (DOC. 167)

Defendant has filed a second motion for partial summary judgment of non-infringement and invalidity of the asserted claims of the '612 and the '197 patent. (Doc. No. 167). Defendant requested that the Court hear oral argument on this motion. Plaintiff has filed a Memorandum in Opposition (Doc. No. 174) to which Defendant has filed a Reply (Doc. No. 184).

In its motion for summary judgment, Medrad argues that the accused devices do not infringe the '612 and '197 patents because the accused devices lack at least two elements of the asserted claims, a moving motor and physical indicia indicating the length of an extender. Medrad also argues that the '612 and '197 patents are invalid because the specifications of both asserted patents fail to satisfy the written description and enablement requirements of 35 U.S.C. § 112. The Court will address Medrad's invalidity argument first.

A. Invalidity of the '612 and 197 Patents

Medrad contends that the '612 and '197 patents are invalid for failure to comply with the written description

and enablement requirements provided in 35 U.S.C. § 112, ¶ 1. That paragraph provides, in pertinent part, as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. § 112, ¶ 1. This paragraph requires both a written description of the specific subject matter claimed and that the description enable one skilled in the art to make and use the claimed invention. *Rohm and Haas Co. v. Mobil Oil Corp.*, 718 F.Supp. 274, 287 (D. Del. 1989), *aff'd*, 895 F.2d 1421 (Fed.Cir. 1990); *see In re Wilder*, 736 F.2d 1516, 1520 (Fed.Cir. 1984), *cert. denied*, *Wilder v. Mossinghoff*, 469 U.S. 1209 (1985) (citations omitted).

B. Written Description

The written description provision requires that the specification of the patent describe the inventions claimed in the patent. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed.Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed.Cir. 1998). The written description must clearly allow those of ordinary skill in the art to recognize that the applicant invented what is claimed. *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996) (quoting *In re Gosteli*, 872 F.2d 1008, 1012, (Fed.Cir. 1989) (citation omitted)). "The adequate written description requirement . . . serves 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how

the specification accomplishes this is not material.'" *In re Alton*, 76 F.3d at 1172 (quoting *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)).

A party arguing that a patent is invalid due to failure to comply with the written description requirement of § 112 carries a heavy burden. Every patent is presumed valid. *National Recovery Technologies, Inc. v. Magnetic Separation Recovery Systems, Inc.*, 166 F.3d 1190, 1195 (Fed.Cir. 1999); *Texas Instruments Inc. v. United States Int'l Trade Comm'n*, 988 F.2d, 1165, 1177 (Fed.Cir. 1993). This presumption of validity includes a presumption that the patent complies with 35 U.S.C. § 112. *National Recovery Technologies*, 166 F.3d at 1195. Thus, a party challenging the validity of a patent bears the burden of establishing invalidity by clear and convincing evidence. *Texas Instruments Inc.*, 988 F.2d at 1177; *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1575 (Fed.Cir. 1984) (stating that the burden of persuasion always remains on the party asserting invalidity); *see also National Recovery Technologies*, 166 F.3d at 1195 (quoting *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed.Cir. 1990), *cert. denied*, 498 U.S. 920 (1990)). Whether a specification complies with the written description requirement of §112 is a question of fact.

Suntiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1334 (Fed. Cir. 1999); *Gentry Gallery*, 134 F.3d at 1479.

Medrad, relying on the conclusions of its experts, argues that the single phrase referring to "physical

indicia" in the specifications of the '612 and '197 patents[34] fails to convey with reasonable clarity that the inventor had possession of the claimed subject matter as of the filing date of the applications for these patents.[35] (*See also*, Doc. No. 167, Exh. 10).

In response, L-F argues that the issue of sufficiency of the written description of the '612 and '197 patents was specifically dealt with by the PTO Examiner during prosecution of the '197 patent. As discussed in great detail

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[34] The phrase referred to by Medrad is "physical indicia on the syringe or extender which indicate the length of the extender." ('669 patent, Abstract, Col. 4, lines 1-3 and '197 patent, col. 3, lines 67-69).

[35] In his declaration, Robert Sturges states:

> 12. Based on lack of disclosure by L-F, the '612 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with "physical indicia" other than, at best, "physical indicia" on the extender related to the length of the extender. The '612 patent contains no description or drawings that teach or even disclose "physical indicia" that are related to syringe capacity or other parameters.

(Doc. No. 167, Exh. 6, ¶ 12).

In his declaration, Rudy Kranys states:

> 23. I have also reviewed L-F's U.S. Patent No. 5,662,612 ("'612 patent") and L-F U.S. Patent No. 5,928,197 ("'197 patent"). Based on my review of '612 and '197 patents, the prosecution histories of the '612 and '197 patents, and the prosecution history of the related abandoned, parent U.S. Patent Application Serial No. 157,823, the L-F '612 and '197 patents only suggest to me, as one highly knowledgeable with respect to medical injectors, an injector and a pre-filled syringe system in which the injector has a detector to identify the length of the extender used with the syringe based on what is identified as "physical indicia" located on the syringe or extender that is used with the syringe.

(Doc. No. 167, Exh. 7, ¶ 23).

in section III(D), the PTO Examiner initially rejected the '197 patent for failure to comply with the written description requirement. After L-F provided a response addressing the PTO Examiner's concerns, the patent was issued with no substantive amendment of the claims or specification. (Doc. No. 174, Exh. 4, Notice of Allowance on 4/1/99, p. 139). Additionally, L-F presents the affidavit of its own expert, Arthur Helmicki, who concludes that the specification of the '612 and '197 patents is sufficient.[36]

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[36] In his affidavit, Helmicki states:

> 21. In his expert report in this matter, Medrad's expert Dr. Sturges, states that he expects" ". . . to testify, based on a lack of L-F's disclosure, that the '612 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with 'physical indicia' other than at best 'physical indicia' on the extender related to the extender position." I disagree. It is my belief that the typical or ordinary person charged with designing control systems for an injector, would be readily able to design and construct a syringe with physical indicia and a sensor for reading those indicia, without regard to whether the indicia are on an extender or relate to properties of an extender.
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> 22. First, as quoted above from his report, Dr. Sturges accepts that the content of the '612 patent would enable a typical syringe/injector designer " . . . to construct or design a syringe with 'physical indicia' . . . on the extender related to the extender position." I agree with this statement. Moreover, I would submit that a designer of ordinary skill in the art, having taken this step, would clearly be able to realize this concept in other ways, to include "physical indicia" on the syringe, as is suggested in the '612 an '197 patents. Further, it is my opinion that a designer of ordinary skill in the art, armed with the contents of the '612 and '197 patents, would be able to carry out this activity in a straightforward manner.
>
> 23. Second, the point at issue here is the design of a device capable not only of automatically detecting "physical indicia" on the syringe but also using this information in order to achieve various automatic control objectives (e.g., remaining volume determination, end of travel shut-off, etc.). With regard to the use

(Continued on following page)

Taking into account Medrad's burden on validity, establishing invalidity by clear and convincing evidence, compounded by the fact that the Court must approach summary judgment with extreme caution, the Court finds that, in light of the prosecution history of the '197 patent and the conclusion of L-F's expert,, there are genuine issues of material fact that preclude summary judgment on the issue of invalidity based on failure to comply with the written description requirement of 35 U.S.C. § 112¶ 1.

2. Enablement

Medrad also contends that the asserted patents fail to satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1. The enablement requirement of § 112 demands "that the patent specification enable 'those skilled in the art to make and use the full scope of the claimed invention without undue experimentation.'" *National Recovery*

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of information about a syringe (however obtained) in performing automatic control, I do not see how the '612 and '197 patents can be faulted for a lack of disclosure. The '612 and '197 patents contain a number of figures (Figures 3-5) together with supporting and detailed description in the specification of the operation of such a system from a block diagram standpoint. This description even includes details of the circuitry necessary for carrying out the design. Moreover, the specification provides a detailed set of flow diagrams (Figure 7) together with associated text description outlining the exact algorithms by which automatic control of the device should be operated. Finally, the '612 and '197 patents have associated with them a microfiche appendix containing the software code needed to run an injector performing automatic control. One could hardly ask for more disclosure. In fact, I would submit that someone of less than ordinary skill in the art, when presented with such a roadmap, would be able to duplicate a device with this functionality.

(Doc. No. 174, Exh. 5, ¶¶ 21-23).

Technologies, 166 F.3d at 1195 (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed.Cir. 1997), *cert denied*, 522 U.S. 963 (1997)) (internal quotation marks and citations omitted). The scope of the claims must be equal to or less than the scope of the enablement, which is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation. *National Recovery Technologies*, 166 F.3d at 1196.

Whether a specification satisfies the enablement requirement of § 112 is a "' . . . conclusion of law and must be supported by facts proved by clear and convincing evidence . . . '" *National Recovery Technologies*, 166 F.3d at 1195 (quoting *Northern Telecom*, 908 F.2d at 941). "While enablement is ultimately a question of law . . . , it is based on underlying factual findings . . . " *Bruning v. Hirose*, 161 F.3d 681, 686 (Fed.Cir. 1998).

As with the written description requirement, a court, when reviewing for enablement, must keep in mind that every patent is presumed valid and the a party challenging its validity bears the burden of establishing invalidity by clear and convincing evidence. *See National Recovery Technologies*, 166 F.3d at 1195; *Texas Instruments*, 988 F.2d at 1177; *ACS Hospital Systems*, 732 F.2d at 1575.

The extent of experimentation required to enable a patent is a key question when analyzing a patent to determine if it meets the requirements of § 112. The Federal Circuit has established the following factors which a court may consider in determining whether a disclosure would require undue experimentation for enablement purposes:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. A court need not review all of the factors. *Id.* The facts of the case determine which factors are relevant. *Id.*

In support of its argument that the specification of the '612 and '197 patents does not meet the enablement requirement of § 112, Medrad relies on the conclusions of its experts, Robert Sturges and Rudy Kranys,[37] that

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[37] In his declaration, Sturges states:

> 12. Based on lack of disclosure by L-F, the '612 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with "physical indicia" other than, at best, "physical indicia" on the extender related to the length of the extender. The '612 patent contains no description or drawings that teach or even disclose "physical indicia" that are related to syringe capacity or other parameters.
>
> * * *
>
> 16. Based on L-F's lack of disclosure, the '197 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with 'physical indicia' other than, at best, 'physical indicia' on the extender related to the length of the extender.

(Doc. 167, Exh. 6, ¶¶ 12, 16).

In his declaration, Kranys states:

> 24. As one highly knowledgeable with respect to medical injectors, I find no teachings in the '612 and '197 patents that would have enabled me to construct an injector and pre-filled or empty syringe system in which the injector uses a detector to detect 'physical indicia' located on the syringe (used with the extender)

(Continued on following page)

the specification would not enable one skilled in the art of medical injectors to design or construct an injector system in which the injector uses physical indicia located on the syringe to determine properties of the syringe other than the length of an extender.

In its response, L-F fails to address Medrad's lack of enablement argument. Despite this failure, L-F has presented evidence in response to Medrad's written description argument that is relevant to Medrad's lack of enablement argument. As with the written description, the issue of enablement of the '612 and '197 patents was raised by the PTO Examiner during prosecution of the '197 patent. After L-F addressed the PTO Examiner's concerns, the patent was issued with no substantive amendment of the claims or specification. (Doc. No. 174, Exh. 4, Notice of Allowance on 4/1/99, p. 139). In addition, L-F's expert, Arthur Helmicki, addressed the issue of enablement in his affidavit and concluded that the specification of the '612 and '197 patent would enable one skilled in the art to create and design an injector system that detected "physical indicia" on a syringe that indicated various properties of the syringe. *Supra*, fn. 36.

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or the extender (that is to be used with the syringe) to identify the length of the extender.

* * *

25. Additionally, I find no teachings in the '612 or '197 patents that would have enabled me to construct an injector and syringe system in which the injector uses a detector to detect "physical indicia" located on the syringe to identify the capacity of the syringe or any other parameter.

(Doc. No. 167, Exh. 7, ¶¶ 24, 25).

As discussed above, the extent of experimentation required to enable a patent is a key issue to be considered by the court when making a determination regarding enablement. Medrad has utterly failed to present any evidence related to this issue. Rather, Medrad has simply presented the conclusory statements of its experts that the specification is not enabling without any factual support. This "evidence" is not sufficient to overcome Medrad's burden of proving lack of enablement by clear and convincing evidence.[38] *In re Brandstadter*, 484 F.2d 1395, 1405-06 (C.C.P.A. 1973) (experts' conclusory statements not sufficient for enablement when no factual support provided to support conclusions). Thus, the Court finds that summary judgment is inappropriate with respect to the issue of invalidity of the '612 and '197 patents based upon lack of enablement.

B. Infringement

In section V(B) of this Order, the Court articulated the law on infringement. Rather than repeat verbatim that summary of the relevant law, the Court refers the parties to that section.

In its motion for summary judgment, Medrad argues that the accused products do not infringe the '612 and '197 patents because the accused products do not use an extender, and thus do not have physical indicia which indicate the length of the extender.

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[38] L-F's evidence on this issue is only slightly more persuasive than Medrad's evidence. However, Medrad, not L-F, has the burden of proof with respect to this issue.

Medrad's argument is based on the assumption that the construction of the claim term "physical indicia" relates exclusively to the "length of the extender." As stated in section III(D), the Court does not adopt this construction of "physical indicia". Therefore, Medrad's argument in this summary judgment motion is irrelevant in light of the Court's construction of the claims.

The Court recognizes the difficulties faced by the parties due to the sequencing of motions in this matter. Therefore, the Court invites the parties to rebrief this argument in light of the Court's construction of the term "physical indicia". ***However, neither party should revisit the claim construction issue in any such briefings.*** Briefings should be confined to the issue of infringement in light of this Court's construction of the term "physical indicia" in section III(D). Defendant Medrad's revised motion is due on November 19, 2001, Plaintiff L-F's response is due on December 10, 2001, and Defendant Medrad's reply is due on December 31, 2001.

In its motion for summary judgment, Medrad also argues that the accused products do not infringe the '612 and '197 patents because the accused products do not have a "motor that moves" and the accused products do not "track the location of said motor."

Medrad's argument is based on its faulty construction of the term "motor" and "tracks location of said motor." As stated in section III(E), the Court does not adopt Medrad's construction of the terms "motor" and "tracks location of said motor." Therefore, Medrad's argument in this summary judgment motion is irrelevant in light of the Court's construction of the claims.

Again, the Court recognizes the difficulties faced by the parties due to the sequencing of motions in this matter. Therefore, the Court invites the parties to rebrief this argument in light of the Court's construction of the terms "motor" and "tracks location of said motor." ***However, neither party should revisit claim construction issues in any such briefings.*** Briefings should be confined to the issue of infringement in light of this Court's construction of the term "motor" and "tracks location of said motor" in section III(E). Defendant Medrad's revised motion is due on November 19, 2001, Plaintiff L-F's response is due on December 10, 2001, and Defendant Medrad's reply is due on December 31, 2001.

Thus, the Court **DENIES**, Defendant's Motion for Partial Summary Judgment of Non-infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. 167), with respect to invalidity. The Court **RESERVES JUDGMENT** on Medrad's motion with respect to infringement.

VIII. PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON COUNTS I-IX OF THE FOURTH AMENDED COMPLAINT (DOC. 169)

Plaintiff filed this motion seeking summary judgment of infringement on specified claims disclosed in the '669 patent, the '261 patent, the '612 patent, and the '197 patent. (Doc. No. 169). Defendant filed a response (Doc. No. 176) to which Plaintiff filed a reply (Doc. No. 185).

Throughout this Order the Court has provided the majority of the factual background and the applicable law relevant to this dispositive motion. The Court will not

repeat that information here but will reiterate any previous statements or provide any previously unmentioned information as is necessary.

A. The '669 and '261 Patents

Based upon the Court's ruling in section V, the Court declares MOOT Plaintiff's Motion for Partial Summary Judgment on Counts I-IX of the Fourth Amended Complaint (Doc. 169) with respect to Counts I and II.

B. The '612 and '197 Patents

Based upon the Court's ruling in section VII(B), the Court invites the parties to rebrief this issue in light of the Court's construction of the terms "physical indicia", "motor", and "tracks location of said motor" in Section III(E). Plaintiff L-F's revised motion is due on November 19, 2001, Defendant Medrad's response is due on December 10, 2001, and Plaintiff L-F's reply is due on December 31, 2001. Thus, the Court **RESERVES JUDGMENT** on L-F's motion with respect to Counts III and IV.

IX. CONCLUSION

In conclusion:

- Plaintiff's Motion for Partial Summary Judgment of Claim Construction (Doc. 164) is **GRANTED** insofar as the Court has construed the claims;
- Defendant's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the Asserted Claims of the '669 and '261 Patents (Doc. 168) is **MOOT**;

- Defendant's Motion for Partial Summary Judgment of Invalidity and Non-Infringement of the Asserted Claims of the '669 and '261 Patents (Doc. 57) is **MOOT IN PART AND GRANTED IN PART**;

- Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. 162) is **NOT RULED ON** because the Court **RESERVES JUDGMENT** pending further briefings;

- Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. 167) is **DENIED IN PART** and **NOT RULED ON IN PART** because the Court **RESERVES JUDGMENT** pending further briefings;

- Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. 169) is **MOOT IN PART** and is **NOT RULED ON IN PART** because the Court **RESERVES JUDGMENT** pending further briefings.

IT IS SO ORDERED

Date: 10-17-01

/s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Liebel-Flarsheim Co.	:	
Plaintiff,	:	
vs.	:	Case C-1-98-858
Medrad Inc.,	:	
Defendant.	:	

ORDER

(Filed Feb. 19, 2002)

This matter is before the Court on multiple motions for partial summary judgment. In an Order filed October 18, 2001 ("the Oct. 18th Order"), the Court ruled on a number of these motions and reserved judgment on the remaining motions pending rebriefing by the parties. (Doc. No. 247). In this Order, the Court will address the revised motions for partial summary judgment (Doc. Nos. 248, 249, and 250/251) filed pursuant to its Oct. 18th Order.

I. GENERAL BACKGROUND

The patents at issue, United States Patent No. 5,662,612 ("the '612 patent") and United States Patent No. 5,928,197 ("the '197 patent"), are part of a series of patents that relate to medical devices known as powered injectors which deliver contrast agents from a syringe into a patient's bloodstream for certain medical diagnostic procedures. (Doc. No. 30, Exhs. 1-4). The '612 and '197 patents, filed on June 26, 1995 and August 28, 1997, respectively, involve the automatic control of the plunger drive in order

to automate its movement.[1] (Doc. No. 30, Exhs. 3 and 4). The injector disclosed in the patents includes structure and control circuitry that detect physical indicia on a syringe, which relate to various physical properties of the syringe. The control circuitry of the injector uses these various physical properties to compute the location of the plunger, which is then used by the control circuitry to determine when to halt the movement of the plunger drive.

Plaintiff Liebel-Flarsheim Co. ("L-F") initiated this lawsuit on November 13, 1998, claiming that Defendant Medrad, Inc. ("Medrad"), through its manufacture, use, marketing, and/or sale of various injectors and syringes, infringed, contributorily infringed, and/or induced infringement of a number of patents, including the '612 and '197 patents. (Doc. Nos. 1, 4, 5, 23, and 30). Numerous partial summary judgment motions have been filed in this matter. (Doc. Nos. 57, 162, 164, 167, 168, and 169). In its Oct. 18th order, the Court disposed of a number of these motions but reserved judgment, in whole or in part, on the following motions:

1. Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own

[1] The '612 and '197 patents, both titled "Controlling Plunger Drives for Fluid Injections in Animals", issued on September 2, 1997 and July 27, 1999, respectively. The '612 and '197 patents are continuations of a patent that was filed on November 27, 1993, but was subsequently abandoned. (Doc. No. 167, Exh. 4). Therefore, the '612 and '197 patents claim an effective filing date of November 27, 1993. Furthermore, as continuation applications, the '612 and '197 patents have the same specifications and drawings.

Patent Which is Prior Art to the Asserted Patents (Doc. No. 162),

2. Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. No. 167), and

3. Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. No. 169).

Per the Court's Oct. 18th Order, the parties have filed the following motions:

1. Defendant Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 249),

2. Defendant Medrad Inc.'s Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. Nos. 250/251), and

3. Plaintiff Liebel-Flarsheim's Resubmitted Motion for Partial Summary Judgment of Infringement on United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 248).

The parties have filed the appropriate memoranda in opposition (Doc. Nos. 256, 257, and 255) and reply briefs

(Doc. Nos. 259, 258, and 262).[2] The Court is now prepared to rule on these motions.[3]

II. DISCUSSION

As a result of the Court's ruling in its Oct. 18th Order, the single remaining issue before the Court is whether the injectors and syringes manufactured and sold by Medrad infringe certain claims of the '612 and '197 patent. In its Oct. 18th Order, the Court discussed in great detail the applicable law relevant to summary judgment, patent claim construction, patent infringement, and patent validity. (Doc. No. 247, pp. 6-14, 5-52, 62-64, and 67-71). The Court will not repeat that discussion here but incorporates it by reference into this Order. Of course, the Court will reiterate any previous statements or provide any previously unmentioned information as is necessary.

Because L-F's motion for summary judgment of infringement (Doc. No. 248) and Medrad's motion for summary judgment of non-infringement and invalidity (Doc. Nos. 250/251) overlap on numerous technical issues, the Court will analyze those motions together.

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[2] The Court has also considered all sur-replies and responsive pleadings filed by the parties. (Doc. Nos. 263, 266, 268, and 270).

[3] Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. No. 162); Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. No. 167), and Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. No. 169) are superseded by the parties' revised motions (Doc. Nos. 259, 258, and 262) and are, therefore, DENIED, on that basis.

A. Infringement of the '612 and '197 Patents

The '612 and '197 patents disclose an injector which automatically controls the advancement and retraction of the plunger drive, freeing the operator of the injector to complete other tasks. (Doc. No. 30; Exh. 3, Col. 3, lines 7-8; and Exh. 4, Col. 3, lines 6-7). L-F claims that Medrad's Envision™ and Vistron® injectors and the syringes compatible with those injectors ("the Accused Injectors" and "the Accused Syringes") infringe certain claims of the '612 and '197 patents. (Doc. No. 30, ¶¶ 21-29 and 72-79). Specifically, L-F alleges that the Accused Injectors and Syringes infringe claims 7, 8, 10, and 11 of the '612[4] patent

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[4] For purposes of the Court's infringement analysis, the relevant claims of the '612 patent are independent claims 7 and 10.

Claim 7 and 10 of the '612 patent state:

7. An injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at a distal end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to a syringe installed on said injector for detecting a physical indicia on said syringe related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the location of a plunger within said syringe relative to an end of said syringe, by relating said electrical signal to the tracked location of said motor.

10. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

(Continued on following page)

and claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, and 27 of the '197 patent ("the asserted claim").[5] (Doc. No. 248, p. 1; Doc. No. 30, Exh. 3 and 4).

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detecting a physical indicia on said syringe installed on said injector, said indicia being related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the location of a plunger within said syringe relative to an end of said syringe by relating said electrical signal to the tracked location of said motor.

(Doc. No. 30, Exh. 3).

[5] For purposes of the Court's infringement analysis, the relevant claims of the '197 patent are independent claims 1, 4, 7, 10, 13, 16, 19, 22, 25, and 27.

Claim 1 and 4 of the '197 patent state:

1. An injector and syringe, comprising:

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector,

a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

(Continued on following page)

4. A method of controlling an injector of the type having a motor which advances and retracts the plunger located within the syringe toward and away from a nozzle at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

(Doc. No. 30, Exh. 4).

Claims 7, 10, 13, 16, 19, and 22 are the same as claims 1 and 4 in all relevant respects except that the physical indicia in those claims relate to the amount of fluid in the syringe, the end of travel position of an injector ram, and the range of travel of an injector ram.

Claim 25 and 27 of the '197 patent state:

25. An injector and syringe, comprising:

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia,

a motor which advances and retracts the plunger within the syringe toward and away from the nozzle to inject fluid into or out of an animal subject, and

a controller comprising:

a control circuit which causes the motor to move and tracks the location of the motor while moving the motor, and

a memory storing an offset value which is related to the capacity of said syringe,

wherein the control circuit is operable obtain an offset value from physical indicia detected on the syringe, and the control circuit computes a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and ceases

(Continued on following page)

The asserted independent claims describe an injector comprised of a syringe, a motor, a detector, and a control circuit. (Doc. No. 30, Exh. 3 and 4). The syringe disclosed in the claims includes physical indicia related to various physical properties of the syringe. (*Id.*) During operation of the injector, the detector described in the claims detects the physical indicia on the syringe and generates an electrical signal representative of such physical indicia. (*Id.*) The control circuit then uses this electrical signal and other information to determine the location of the plunger drive. (*Id.*) The location of the plunger drive is then used by the control circuit to determine when to halt the movement of the plunger drive. (*Id.*) Several of the asserted claims also describe the method of operating such an injector. (*Id.*).

Medrad argues that the Accused Injectors and Syringes do not infringe the asserted claims because the

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motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

27. A method of controlling an injector of the type having a motor which advances and retracts a plunger within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, comprising:

causing the motor to move and tracking the location of the motor while moving the motor,

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of said syringe, to obtain an offset value,

computing a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and

ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

(Doc. No. 30, Exh. 4).

Accused Injectors and Syringes are missing a number of elements disclosed in the claims. (Doc. Nos. 250/251, p.1). In particular, Medrad argues that the Accused Injectors and Syringes are missing the following claim elements:

- a motor which advances and retracts a plunger;
- adapted for use with syringe assemblies;
- a detector located proximate to a syringe;
- a detector located proximate to the syringe;
- detecting a physical indicia on a syringe;
- physical indicia on said syringe relating to the capacity of the syringe, the distance of the plunger from the end of the syringe, the amount of fluid in the syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value;
- relating said electrical signal to the tracked location of said motor;
- using said electrical signal and the tracked location of said motor; and
- an electrical signal representative of said physical indicia.

(Doc. Nos. 250/251, pp. 3-4). Medrad argues that because the Accused Injectors and Syringes are missing these elements, they cannot infringe the '612 and '197 patents as a matter of law, and Medrad is, therefore, entitled to summary judgment of non-infringement of the '612 and '197 patents. (Doc. Nos. 250/251, pp. 4, 27-28).

Before addressing the parties' arguments in more detail, it is worth noting that L-F is only claiming the Accused Injectors and Syringes literally infringe the asserted claims of the '612 and '197 patent. (Doc. No. 248, pp. 15-16, and 20). L-F has not argued infringement under the doctrine of equivalents nor responded to Medrad's argument of non-infringement under this doctrine.[6] Literal infringement occurs when the accused product is precisely described in a patent claim. *SRI Int'l v. Matsushita Electric Corp.*, 775 F.2d 1107, 1123 (Fed.Cir. 1985). It is well recognized that if any claim limitation is absent from the accused device, there can be no literal infringement as a matter of law. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed.Cir. 1999), *cert. denied*, 529 U.S. 1066 (2000) (quoting *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed.Cir. 1998)). Thus, if even one of the elements of the asserted claims is missing from the Accused Injectors and/or Syringes, they cannot infringe the '612 and '197 patents as a matter of law.

With this principle in mind, the Court finds that it need not address each and every claim element identified as missing by Medrad because it finds that the Accused Syringes are missing at least one critical element of the

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[6] In its summary judgment motion of non-infringement, Medrad notes that it is unclear whether L-F is alleging infringement of the '612 and '197 patents under the doctrine of equivalents and argues that even if L-F is making such an allegation, the Accused Injectors and Syringes do not infringe the patents under the doctrine. (Doc. Nos. 250/251, p. 9, fn. 4). In its memorandum in opposition, L-F does not respond to or even acknowledge Medrad's non-infringement under the doctrine of equivalents argument. (Doc. No. 257). Furthermore, in its own summary judgment motion of infringement, L-F only alleges that the Accused Injectors and Syringes literally infringe the '612 and '197 patents (Doc. No. 248, p. 20).

asserted claims – physical indicia relating to the capacity of the syringe, the distance of the plunger from the end of the syringe, the amount of fluid in the syringe, the end of travel position of an injector ram, or the range of travel of an injector ram or physical indicia that provides an offset value[7]. Because the Accused Syringes are missing this claim element, it follows that the Accused Injectors are missing any claim elements that rely on the existence of such physical indicia.

Before proceeding further in its analysis, the Court believes it would be helpful to describe the relevant aspects of the operation of the Accused Injectors and Syringes, a factual issue that does not appear to be in dispute by the parties. The Accused Injectors are compatible with three types of syringes, a 200 ml empty syringe, a 125 ml empty syringe, and a Bracco prefilled syringe[8,9].

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[7] In its Oct. 18th Order, the Court construed the term "physical indicia" as a tangible mark on a syringe relating to various properties of the syringe such as capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value. (Doc. No. 247, p. 45). It has become clear to the Court during its analysis for this Order that Claim 25 of the '197 patent does not describe physical indicia in terms of "relating to" an offset value. (Doc. No. 30, Exh. 4). Rather, according to Claim 25, the information detected from the physical indicia actually constitutes the offset value, "a control circuit obtain[s] an offset value from physical indicia detected on the syringe". (Doc. No. 30, Exh. 4; Doc. No. 248, Exh. 16, Helmicki Aff., ¶ 7(f)). Thus, the Court must clarify its construction of the term "physical indicia" with respect to an offset value as "a tangible mark that provides an offset value".

[8] Bracco pre-filled syringes are available in 75 ml, 100 ml and 150 ml sizes. (Doc. Nos. 250/251, Exh. 5, ¶ 8).

[9] The Vistron injector can also sense an adapter that allows for a fourth type of syringe. (Doc. Nos. 250/251, Exh. 5, Braunstein Decl., ¶ 10).

(Doc. Nos. 250/251, Exh. 5, Braunstein Decl., ¶ 8). Each of these syringes has flanges to the rear of the syringe. *(Id.* at ¶6). Depending on the type of syringe, the flanges have indents at various locations or have no indents at all. *(Id.* at ¶6). When the syringe is installed on the injector, these indent(s)/lack of indents interact with a series of pins attached to the injector. (*Id.*). A pin is depressed or released depending on the presence or absence of an indent. (*Id.*). Based on the position of these pins, sensors send electrical signals, representing a value of either a 1 or 0, to the injector head microprocessor which interprets these signals to determine the type of syringe installed. *(Id.* at ¶6-7). Depending on the syringe type, the injector head microprocessor generates a binary reference number of 1, 2, or 4, for the 125 ml empty syringe, the 200 ml empty syringe, and the Bracco prefilled syringe, respectively.[10]

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[10] In his affidavit, L-F's expert, Arthur Helmicki, states that "[t]he Medrad Brief . . . states that the injector microprocessor only receives a value of 1, 2 or 4 from the optical sensors reading the detents . . . ". (Doc. No. 257, Exhibit 8, Post-Claim Construction Affidavit of Arthur J. Helmicki, ¶ 12). The description in Medrad's brief, which is based on the declaration of Thomas Braunstein, Manager of Advanced Manufacturing Engineering for Medrad, clearly states that the injector microprocessor generates the values of 1, 2, or 4 from the electrical signals sent by the sensors. (Doc. No. 251, p. 6). In his declaration, Braunstein explains that the injector microprocessor receives an electrical signal of 0 or 1 for each pin depending on the position of the pin. (Doc. Nos. 250/251, Exh.5, Braunstein Decl., ¶ 6). Based on the configuration of these values, the microprocessor determines the type of syringe installed and then generates a value of 1, 2, or 4 as a reference number. *(Id.* at ¶7). Thus, the injector microprocessor does not ***receive*** values of 1, 2, or 4 but ***generates*** these values based on information received from the sensors.

Although Helmicki misstates Medrad's description of the operation of the injector, it appears from the following description in his affidavit that he correctly understands the operation of the injectors:

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(*Id.* at ¶7). The head microprocessor communicates the appropriate reference number to the system microprocessor, which then uses the reference number as an index to look up various syringe parameters in a table. (Doc. Nos. 250/251, p. 6).

Medrad argues that because the only information gleaned from the indents is the "type" of syringe, the Accused Syringes do not have physical indicia as described in the asserted claims.[11] (Doc. Nos. 250/251, p. 16-18). The

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> The determination of the syringe configuration [type][1] is made by the software source code used in the Envision and Vistron CT injectors based upon the electrical signals generated by the switches on the injector.
>
> (Doc. No. 248, Exh. 16, Helmicki Aff., ¶ 10).
>
> [1]Medrad assumes that the term configuration, as used by Helmicki, has the same meaning as the term type. (Doc. No. 255, p. 7, fn. 4). L-F does not dispute this assumption.

For purposes of the Court's analysis, whether the injector microprocessor receives the values of 1, 2, or 4 from the sensors or generates these values based on electrical signals from the sensors is not critical.

[11] The Court has construed physical indicia as a "tangible mark" relating to various syringe properties. The parties do not dispute that the Bracco prefilled syringes and the 100 ml non-Medrad syringes used with the Vistron injector adapter do not have any indents on the syringe flanges. Despite L-F's argument to the contrary, no reasonable jury could conclude that a complete absence of indents constitutes a "tangible mark." (Doc. No. 257, p. 14-15). *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986). Therefore, the Bracco prefilled syringes and the 100 ml non-Medrad syringes are missing "physical indicia" as that term is used in the asserted claims.

Medrad also argues that the term "physical indicia" is plural and because the Accused Syringes that have indents only have one indent sensed during the operation of the injector, these syringes do not have physical indicia as contemplated by the asserted claims. (Doc. Nos. 250/251, pp. 14-15). This issue is not relevant to the Court's analysis and will, therefore, not be resolved at this time. Furthermore, the

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asserted claims disclose physical indicia related to various syringe properties such as capacity of the syringe, distance of the plunger from the end of the syringe, amount of fluid in the syringe, end of travel position of an injector ram, or range of travel of an injector ram or physical indicia that provide an offset value. As Medrad correctly points out, these properties clearly do not include the "type" of syringe installed on the injector. (Doc. Nos. 250/251, pp. 2 and 16). Thus, according to Medrad, the Accused Syringes are missing the "physical indicia" claim element.

L-F counters that because Accused Injectors use the "type" of syringe to ultimately determine the various syringe properties described in the claims (by looking up the information in a table and using that information to determine syringe properties), the indents are physical indicia related to various syringe properties as disclosed in the asserted claims. (Doc. No. 257, p. 22; Doc. No. 262, p. 8).

The difference in the parties' infringement analyses comes down to an issue of claim construction. Medrad's analysis rests on its construction of the term "related to"

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parties should not assume the Court is using the term "physical indicia" in either a plural or singular form in this Order.

Additionally, Medrad contends that the term "physical indicia" requires that information be "encoded" on the syringe. (*See* Doc. Nos. 250/251, pp. 23-24). Medrad argues that the indents on the Accused Syringes do not have any information encoded in them. (Doc. Nos. 250/251, pp. 23-24). Therefore, according to Medrad, the Accused Syringes do not have physical indicia as required by the claims. (Doc. Nos. 250/251, pp. 23-24). This issue is not relevant to the Court's analysis and will, therefore, not be resolved at this time.

as describing a direct one-to-one relationship.[12] According to Medrad, the asserted claims require that the information detected from the physical indicia must actually be the capacity of the syringe, the distance of the plunger from the end of the syringe, the amount of fluid in the syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value. (Doc. Nos. 250/251, p. 19). L-F, on the other had, views the term "related to" as encompassing direct and indirect relationships. As such, L-F argues that the physical indica are "related to" various syringe properties if the information detected from physical indicia is the actual syringe properties or is merely used in some manner to determine syringe properties, as in the case of the Accused Injectors which use the information detected from the physical indicia as an index to look up syringe parameters in a table and then use those parameters to determine various syringe properties. (Doc. No. 257, p. 22; Doc. No. 262, p. 8).

Questions of claim construction are questions of law to be decided by the court. *Wang Labs., Inc. v. America Online, Inc.,* 197 F.3d 1377, 1380-81 (Fed.Cir. 1999). When construing a claim term, the court must first rely on the intrinsic evidence, *i.e.*, the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1582 (Fed.Cir. 1996); *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed.Cir. 1995), *aff'd,* 517 U. S. 370 (1996)). Extrinsic evidence should not be considered unless the intrinsic evidence does

[12] The Court did not construe the term "related to" in its Oct. 18th Order. The Court used the term in its definition of the term "physical indicia" but took no position on the meaning of the term "related to" as it is used in the asserted claims.

not resolve an ambiguity in a challenged claim. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed.Cir. 1999).

In the present case, the meaning of the term "related to" is readily apparent from the language of the asserted claims themselves. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed.Cir. 2001) (In claim construction, the court first considers the language of the claim.). The language of the asserted independent claims, except Claim 27 of the '197 patent, is virtually identical except that each claim refers to a different syringe property. For purposes of the Court's analysis, it will use the claim language of Claim 7 of the '197 patent as an example and will note any differences in the other claims' language as appropriate.[13]

The pertinent claim language of Claim 7 of the '197 patent states as follows:

> An injector and syringe, comprising:
>
> a syringe having . . . physical indicia related to the amount of fluid in the syringe . . . , and . . .
>
> a controller in the injector . . . comprising:
>
> a detector . . . for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and a control circuit . . . wherein said control computes

[13] Independent Claims 7 of the '612 and 1, 7, 13, 19, and 25 of the '197 patent describe the injector claimed in the patents. (Doc. No. 30, Exhs. 3 and 4). Independent Claims 10 of the '612 patent and 4, 10, 16, 22, and 27 of the '197 patent describes methods of using an injector which correspond to the claims describing the injector. (*Id.*).

> the amount of fluid in said syringe, using said electrical signal and the tracked location of said motor.

From this language, one can conclude that the after detecting the physical indicia on the syringe, a detector located in the injector generates an electrical signal that represents the information detected from the physical indicia:

> a detector . . . for detecting the physical indicia on said syringe, and ***generating an electrical signal representative of said physical indicia,*** and

The control circuit of the injector then uses this electrical signal and the tracked location of the motor to compute various syringe properties:

> control circuit ***computes***[14] ***the amount of fluid*** in said syringe, ***using <u>said</u> electrical signal***[15] and the tracked location of said motor.[16]

Of key importance to the Court's analysis is that the electrical signal referenced in the asserted claims is

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[14] Claim 13 of the '197 patent uses the term "determines" rather than "computes". The parties have not argued nor does it appear that this difference in language has any significance.

[15] Claim 7 of the '612 patent uses the term "by relating said electrical signal" rather than "using said electrical signal". The parties have not argued nor does it appear that this difference in language has any significance.

[16] Claim 19 of the '197 patent computes the "range of travel of said ram" using the electrical signal without reference to the tracked location of the motor.

generated by the detector and not the control circuit.[17] It is the signal generated by the detector that is used in the computation of various syringe properties. The claim language does not describe using the electrical signal generated by the detector to ascertain information from another source and then using this ascertained information to compute syringe properties. Thus, the information from the physical indicia that is represented by the electrical signal generated by the detector must be of the type that can be directly used in the computation of various syringe properties without reference to some outside source of information.[18] Under the plain language of the

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[17] L-F's expert, Helmicki, states the following in his affidavit:

> [Medrad's] assertion is based upon the erroneous assumption that the "electrical signal" referenced in the claims is, and can only be, the signal output by the optical sensors (slotted detectors) themselves, excluding the multiple electrical signals derived from the output of the optical sensors, which also represent the syringe information encoded in the indicia.
>
> (Doc. No. 257, Exh. 8, Helmicki Post-Claim Construction Aff., ¶ 10).

This excerpt demonstrates that L-F's argument is based on the assumption that the electrical signal disclosed in the claims does not necessarily have to be the same electrical signal generated by the detector. L-F's (and Helmicki's) assumption is incorrect. The ***only*** electrical signal described in the claims is the original electrical signal generated by the detector.

[18] Claims 25 and 27 do not track the language of the other asserted claims. As already discussed in footnote 7, the physical indicia described in Claim 25 constitutes an actual offset value rather than just relating to an offset value. Claim 27, which describes the method of controlling an injector, states in pertinent part that:

> A method of controlling an injector . . . comprising:
>
> detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of said syringe, to obtain an offset value, . . .
>
> (Doc. No. 30, Exh. 4).

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asserted claims, therefore, physical indicia is/are "related to" various syringe properties when the information detected from the physical indicia is/are the actual syringe properties or can be directly used in the computation of the various syringe properties without reference to some other source of information.

Thus, the Court adopts neither parties' proposed construction of the term "related to" as it is used in the asserted claims.[19] Rather, the Court finds that the term "related to" encompasses both a direct and indirect relationship, with the indirect relationship being limited to information that can be directly used in the computation

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At first glance, it would appear that the term "obtain", as it used in Claim 27, is not the same as the term "compute" and could, arguably, encompass references to an outside source of information. However, the term "obtain" must be read in light of the specification of the '197 patent, which states that "the offset value may be automatically computed by detecting physical indica on the syringe or extender which indicates the length of the syringe." (Doc. No. 30, Exh. 4, Col. 3, line 1 – Col. 4, line 1-2). Thus, the specification equates the term "obtain" with the term "compute".

[19] L-F argues that its construction of the term "related to" is supported by the deposition testimony of Thomas Braunstein, Medrad's 30(b)(6) witness. L-F is incorrect. First, Braunstein's deposition testimony is irrelevant to the Court's claim construction analysis because the Court can construe the term "related to" based solely on the intrinsic evidence. Therefore, the Court should not rely on any extrinsic evidence, such as Braunstein's deposition testimony. Second, Braunstein's deposition testimony regarding the relationship of the indents on the Accused Syringes to various syringe properties is of little assistance to the Court because Braunstein was not testifying about such relationships in terms of the Court's construction of the term "relate to" as it is used in the asserted claims. Consequently, Braunstein's deposition testimony does not support L-F's proposed claim construction. Furthermore, despite L-F's argument to the contrary, there is nothing inconsistent between Braunstein's deposition testimony and his Second Post-Claim Construction Declaration. (Doc. No. 262, pp. 6-7).

of the various syringe properties without reference to some other source of information.

Having construed the meaning of the claims, the Court must now apply the asserted claims to the Accused Injectors and Syringes, which is a question of fact. *Wang Labs.*, 197 F.3d at 1380-81. As such, summary judgment is only appropriate if the Court finds that, when viewing the evidence in the light most favorable to L-F, no reasonable jury could conclude the Accused Injectors and Syringes infringe the '612 and '197 patents. *See Anderson*, 477 U.S. at 250.

As already explained, the information generated by the sensors from the indent(s)/lack of indents on the Accused Syringes are the values of 1 or 0 for each sensor, which are used by the microprocessor to generate reference numbers of 1, 2, or 4. None of these values or reference numbers[20], standing alone, can be used to compute the various syringe properties disclosed in the asserted claims. It is only by referencing some other source of information, a table, that the injector can ascertain the information necessary to determine various syringe properties. Thus, the information gleaned from the indent(s)/lack of indents is not the type of information that can be used to compute syringe properties without referencing some other source of information. Consequently,

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[20] Because of the confusion created by Helmicki's affidavit and mindful that it should consider the evidence in the light most favorable to L-F, the Court is considering the reference numbers generated by the microprocessor in its infringement analysis. In reality, however, the electrical, signals representing the values of 1 or 0 generated by the sensors are the only electrical signals that should actually be considered. *See supra* fn. 10.

the information detected from the indent(s)/lack of indents is not "related to" various syringe properties as that term is used in the asserted claims. Thus, any reasonable jury would find that the Accused Syringes are missing the "physical indicia" claim element because any information detected from the physical indicia[21] does not "relate to" the various syringe properties as required by the asserted claims. Furthermore, it follows that any reasonable jury would find that the Accused Injectors are missing any claim elements that rely on the existence of such physical indicia.

Because the Accused Injectors and Syringes are completely missing an essential element of the claims and do not appear to have a substantial equivalent of that element, they do not infringe the '612 and '197 patents, either literally or under the doctrine of equivalents, and Medrad is, therefore, entitled to summary judgment of non-infringement. *Elkay Mfg. Co.*, 192 F.3d at 980 (No literal infringement if claim limitation is missing.); *Vehicular Technologies Corp. v. Titan Wheel International, Inc.*, 141 F.3d 1084, 1089 (Fed. Cir. 1998) (No infringement under the doctrine of equivalents if substantial equivalent of a claim limitation is missing).

Because the Court can resolve the question of infringement of the '612 and '197 patents on the forgoing issue, it need not, at this time, resolve the other numerous and varied issues raised by the parties. To avoid any confusion in any further proceeding on this matter, the

[21] The Court is assuming the indents on the Accused Syringes constitute a "tangible mark" for purposes of this analysis only. The Court is not resolving this issue at this time.

Court wishes to make it clear that it is not resolving any of the following issues in this or any other order issued to date in this case:

- whether the indents on the Accused Syringes constitute a tangible mark;
- whether physical indicia, as used in the claims, is plural or singular;
- whether L-F admitted during prosecution of the '612 patent that the apparatus and method used by the Accused Injectors to determine the type of syringe in place in the injector is not covered by the asserted claims;
- whether the Accused Injectors use an electrical signal representative of said physical indicia while moving the motor[22];
- whether the Accused Injectors are adapted for use with syringe assemblies;
- whether the indents on the Accused Syringes encode information;
- whether Medrad's injectors have a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia;

---

[22] To eliminate any confusion created by its Oct. 18th, the Court construes the term "motor" as a stationary mechanism that rotates causing the movement of the gears in the gearbox and the term "tracking the location of the motor" as the monitoring of the rotation of the motor.

- whether Medrad's injectors have a motor which advances and retracts the plunger; and
- whether Medrad's injectors and syringes have an offset value.

Thus, the Court **GRANTS**, with respect to non-infringement, Defendant Medrad Inc.'s Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. Nos. 250/251), and declares the motion **MOOT** with respect to invalidity. The Court **DENIES** Plaintiff Liebel-Flarsheim's Resubmitted Motion for Partial Summary Judgment of Infringement on United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 248).

B. Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art

Based upon the Court's ruling in Section A regarding non-infringement, the Court declares **MOOT** Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 249).

C. Motions to Strike

In conjunction with its revised briefings, L-F filed a Motion to Strike the Post-Claim Construction Declaration of Joseph B. Havrilla (Doc. No. 253) and a Motion to Strike Portions of Medrad's Memorandum in Support of its Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the

'612 and '197 Patents and to Strike In Its Entirety Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents because Medrad Practices the Prior Art (Doc. No. 254). Based upon the Court's ruling in Section A regarding non-infringement, the Court declares these motions to strike **MOOT.**

III. CONCLUSION

In conclusion:

- Defendants Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 249) is **MOOT,**
- Defendant Medrad Inc.'s Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. Nos. 250/251) is **GRANTED IN PART** and declared **MOOT IN PART**, and
- Plaintiff Liebel-Flarsheim's Resubmitted Motion for Partial Summary Judgment of Infringement on United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 248) is **DENIED**;
- Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. No. 162) is **DENIED,**

- Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. No. 167) is **DENIED**,

- Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. No. 169) is **DENIED**,

- Plaintiff Liebel-Flarsheim's Motion to Strike the Post-Claim Construction Declaration of Joseph B. Havrilla (Doc. No. 253) is **MOOT**;

- Plaintiff Liebel-Flarsheim's Motion to Strike Portions of Medrad's Memorandum in Support of its Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents and to Strike In Its Entirety Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 254) is **MOOT**; and

- Defendant Medrad's Motion for Leave to File a Sur-Reply to Plaintiff Liebel-Flarsheim Company's Reply Memorandum in Support of its Resubmitted Motion for Partial Summary Judgment of Infringement of United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 263) is **GRANTED**;

- Defendant Medrad's Motion for Leave to File a Sur-Reply to Plaintiff Liebel-Flarsheim Company's Reply Memorandum in Support of its Motion to Strike Pursuant to Fed. R. civ. P. 37(C) (Doc. No. 267) is **GRANTED**; and

- Plaintiff Liebel-Flarsheim Company's Motion for Leave to File Sur-Reply to Medrad's Motion for Leave to File a Sur-Reply to Plaintiff Liebel-Flarsheim Company's Reply Memorandum (Doc. No. 270) is **GRANTED**.

IT IS SO ORDERED

Date 2-15-02 /s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District
Judge

United States Court of Appeals
for the Federal Circuit

03-1082, -1165

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT INC.,

Plaintiffs-Appellants,

v.

MEDRAD, INC.,

Defendant-Cross Appellant.

ORDER

(Filed Apr. 2, 2004)

A combined petition for panel rehearing and for rehearing en banc having been filed by the CROSS-APPELLANT, and a response thereto having been invited by the court and filed by the APPELLANTS, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on April 9, 2004.

FOR THE COURT,

/s/ Jan Horbaly (AV)
Jan Horbaly
Clerk

Dated: April 2, 2004

cc: J. Robert Chambers
Frederick H. Colen

LIEBEL-FLARSHEIM CO V MEDRAD INC, 03-1082, -1165
(DCT – 98-CV-858)

* *
* *
* Note: Pursuant to Fed. Cir. R. 47.6, this order is not *
* citable as precedent. It is a public record. *
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(2)

Supreme Court, U.S.
FILED

04-32 JUL 1 - 2004

No. _____

OFFICE OF THE CLERK

In The
Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT, INC.,

Respondents.

**On Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

SUPPLEMENTAL APPENDIX

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3.	United States Patent No. 5,662,612	Pat. 47 – Pat. 68
4.	United States Patent No. 5,928,197	Pat. 69 – Pat. 92

US005456669A

United States Patent [19]

Neer et al.

[11] Patent Number: 5,456,669

[45] Date of Patent: Oct. 10, 1995

[54] **METHOD OF FRONT LOADING AN INJECTOR AND INJECTING FLUID INTO ANIMALS THEREWITH**

[75] Inventors: **Charles Neer**, Milford; **Frank M. Fago**, Mason, both of Ohio; **Paul E. Dieterlen**, Covington, Ky.; **James H. Goethel**, Cincinnati, Ohio

[73] Assignee: **Liebel-Flarsheim Company**, Cincinnati, Ohio

[21] Appl. No.: **158,765**

[22] Filed: **Nov. 30, 1993**

Related U.S. Application Data

[62] Division of Ser. No. 881,782, May 11, 1992, Pat. No. 5,279,569, which is a division of Ser. No. 712,110, Jun. 7, 1991, Pat. No. 5,300,031.

[51] **Int. Cl.**[6] **A61M 37/00**

[52] **U.S. Cl.** **604/154**; 604/155

[58] **Field of Search** 604/131, 151, 604/152, 154, 155

[56] **References Cited**

U.S. PATENT DOCUMENTS

1,988,480	1/1935	Campkin .	
2,627,270	2/1953	Glass .	
2,946,334	7/1960	Jungst et al. .	
2,956,563	10/1960	Sarnoff .	
3,115,135	12/1963	Sarnoff .	
3,348,545	10/1967	Sarnoff et al. .	
3,395,704	8/1968	Frey et al. .	
3,631,847	1/1972	Hobbs, II .	
3,701,345	10/1972	Heilman .	
3,752,145	8/1973	Runnells et al. .	
3,812,843	5/1974	Wootten et al. .	
3,880,138	4/1975	Wootten et al. .	
4,006,736	2/1977	Kranys et al. .	
4,150,672	4/1979	Whitney et al. .	
4,267,836	5/1981	Whitney et al.	604/154
4,269,185	5/1981	Whitney et al. .	
4,273,122	6/1981	Whitney et al.	604/155
4,342,312	8/1982	Whitney et al.	604/152
4,345,595	8/1982	Whitney et al. .	
4,351,335	9/1982	Whitney et al.	604/154
4,405,318	9/1983	Whitney et al. .	
4,465,473	8/1984	Ruegg .	
4,634,431	1/1987	Whitney et al. .	
4,677,980	7/1987	Reilly et al.	604/154
4,695,271	9/1987	Goethel	604/154
4,744,786	5/1988	Hooven .	
4,854,324	8/1989	Hirschman et al. .	
4,869,720	9/1989	Chernack .	
5,002,538	3/1991	Johnson .	
5,007,904	4/1991	Densmore et al. .	
5,098,386	3/1992	Smith .	

FOREIGN PATENT DOCUMENTS

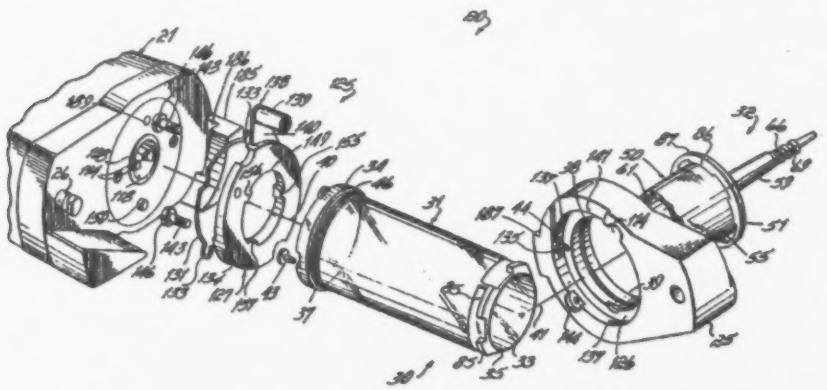
0143895	6/1985	European Pat. Off. .
0346950	12/1989	European Pat. Off. .
0362484	4/1990	European Pat. Off. .

Primary Examiner—John G. Weiss
Attorney, Agent, or Firm—Wood, Herron & Evans

[57] **ABSTRACT**

An animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is loadable and unloadable into and from the injector through the open front end of a pressure jacket of the injector, thereby permitting replacement without retraction of the syringe plunger drive or disconnection of the injection tubing. The syringe is provided with a pressure restraining front end, such as an integral or removable cap with structure such as threads that lock the syringe to the front end of the jacket by mating with threads on the jacket. A mechanism in the injector, which includes, for example, a key on cam ring operated by a lever with one hand of an operator, interacts with structure such asymmetrically spaced notches on the back end of the syringe to, for example, rotate the syringe and simultaneously translate or rotate a coupling on the syringe plunger into and out of engagement with the plunger drive in the injector.

37 Claims, 11 Drawing Sheets



Pat. 1

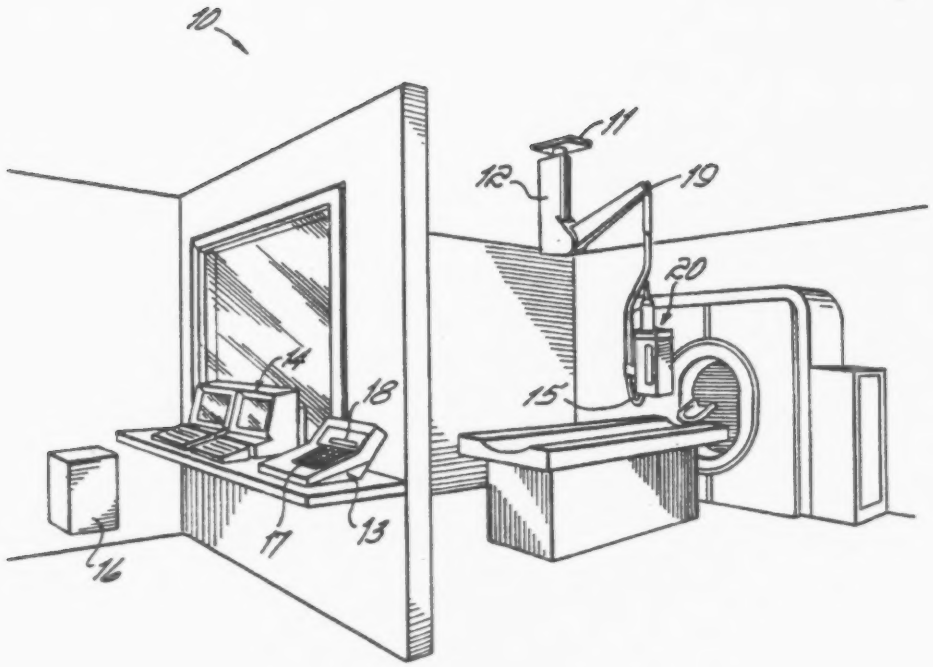


FIG. 1

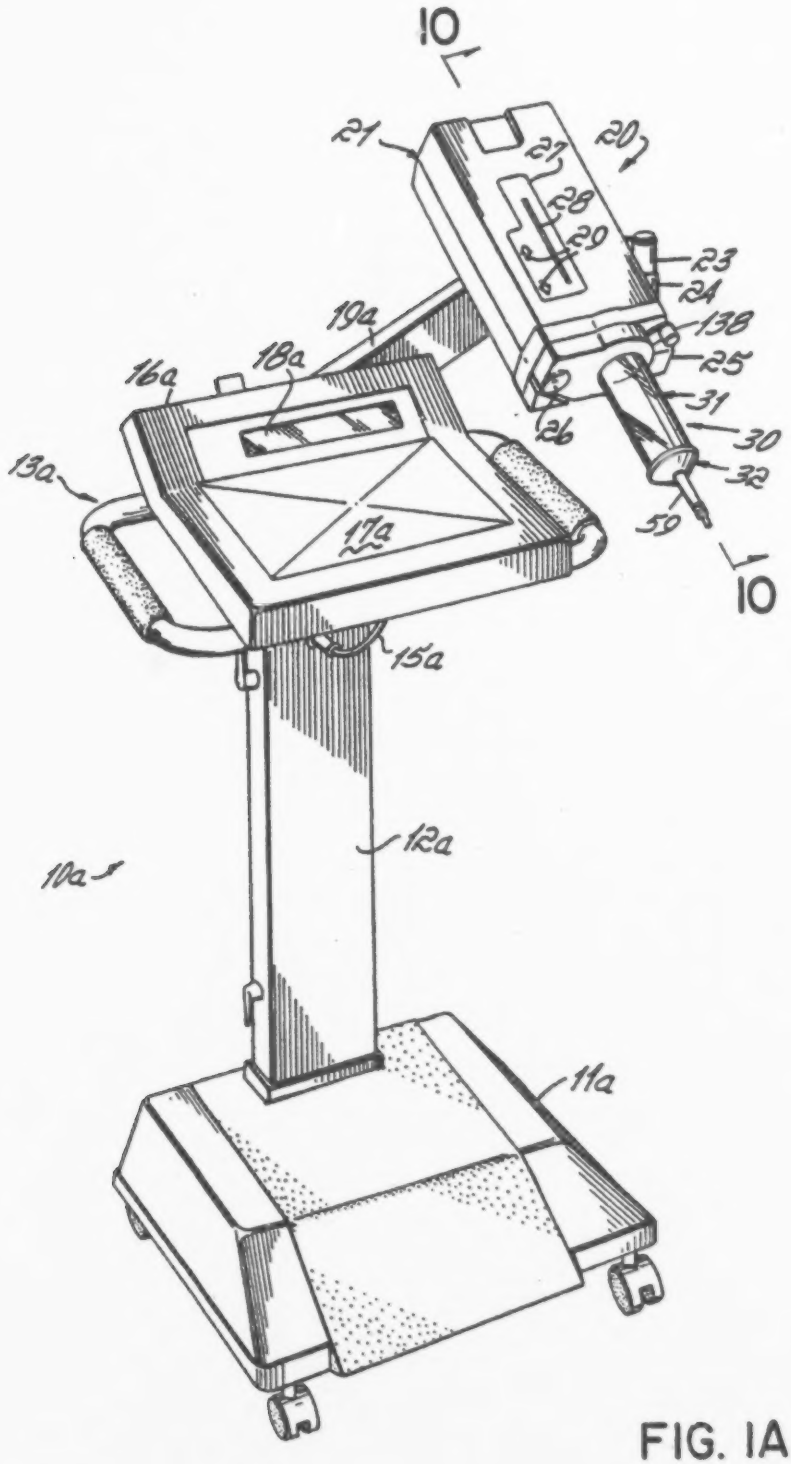

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FIG. 1A

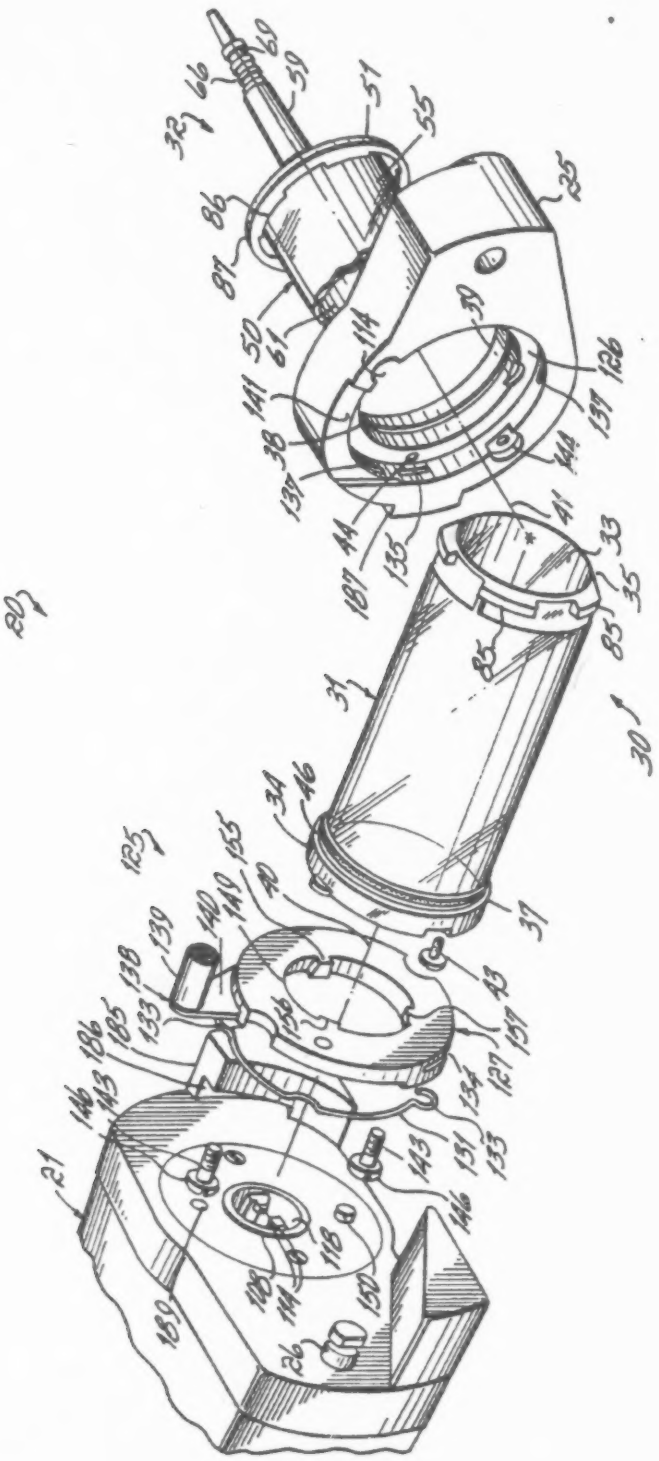


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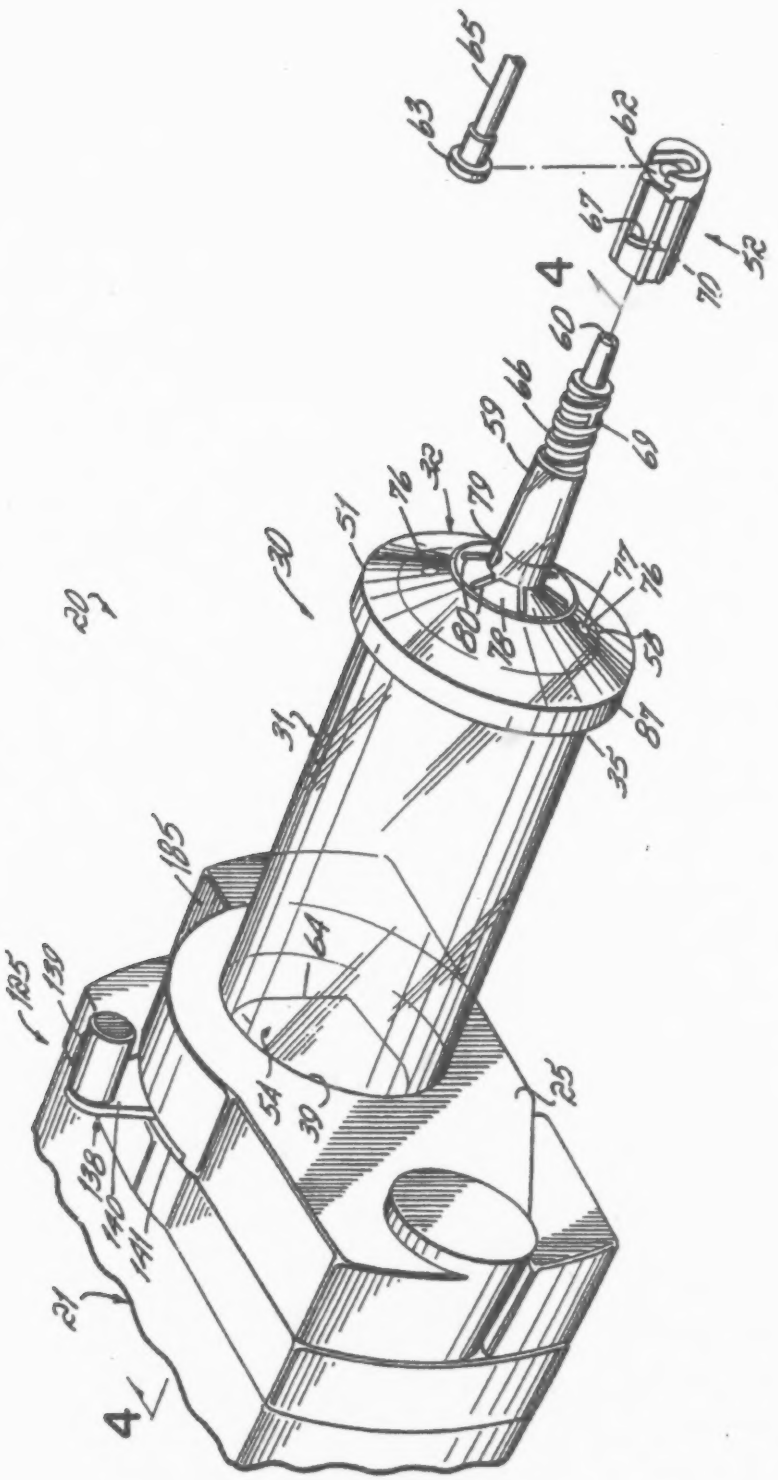

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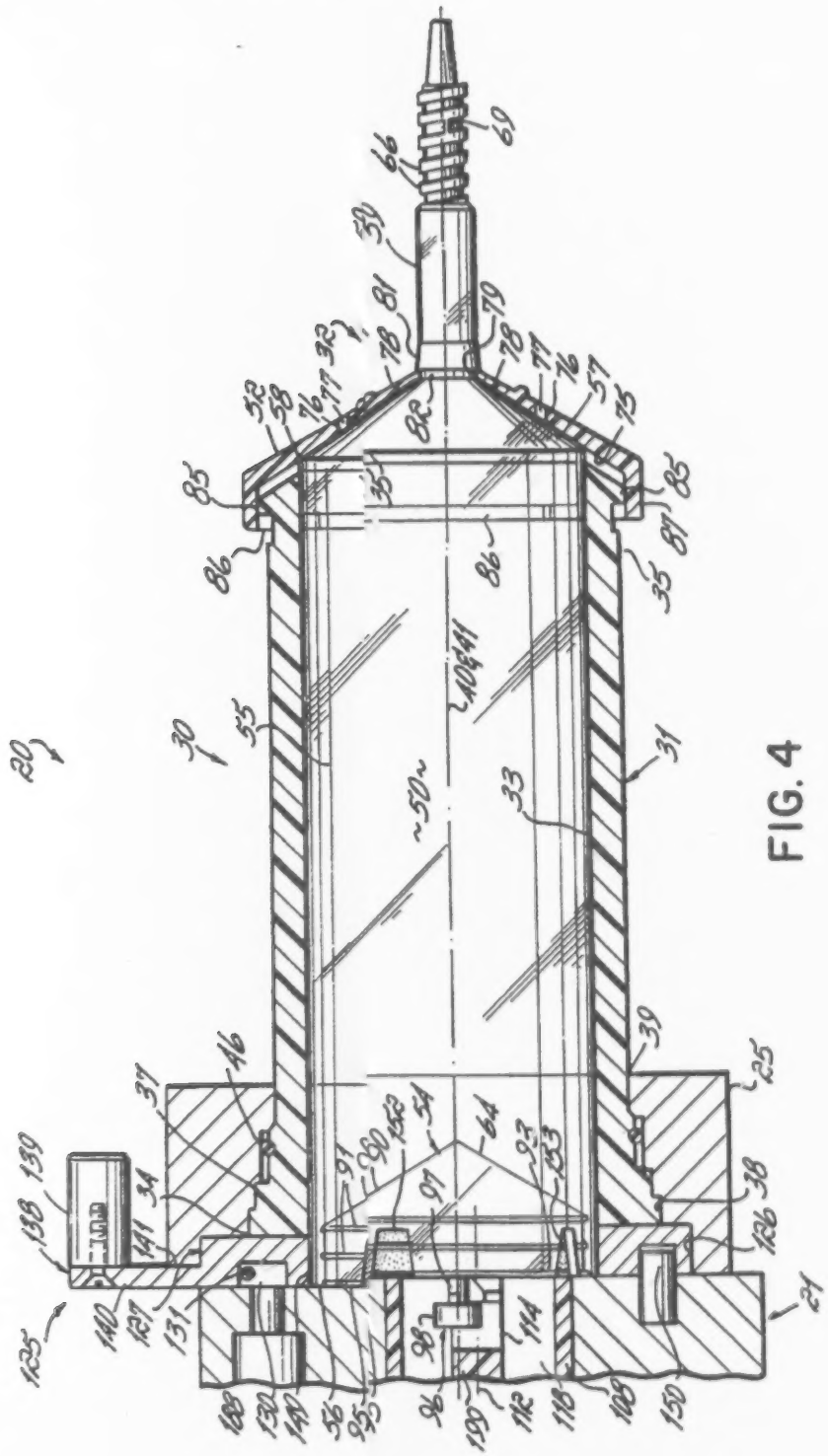


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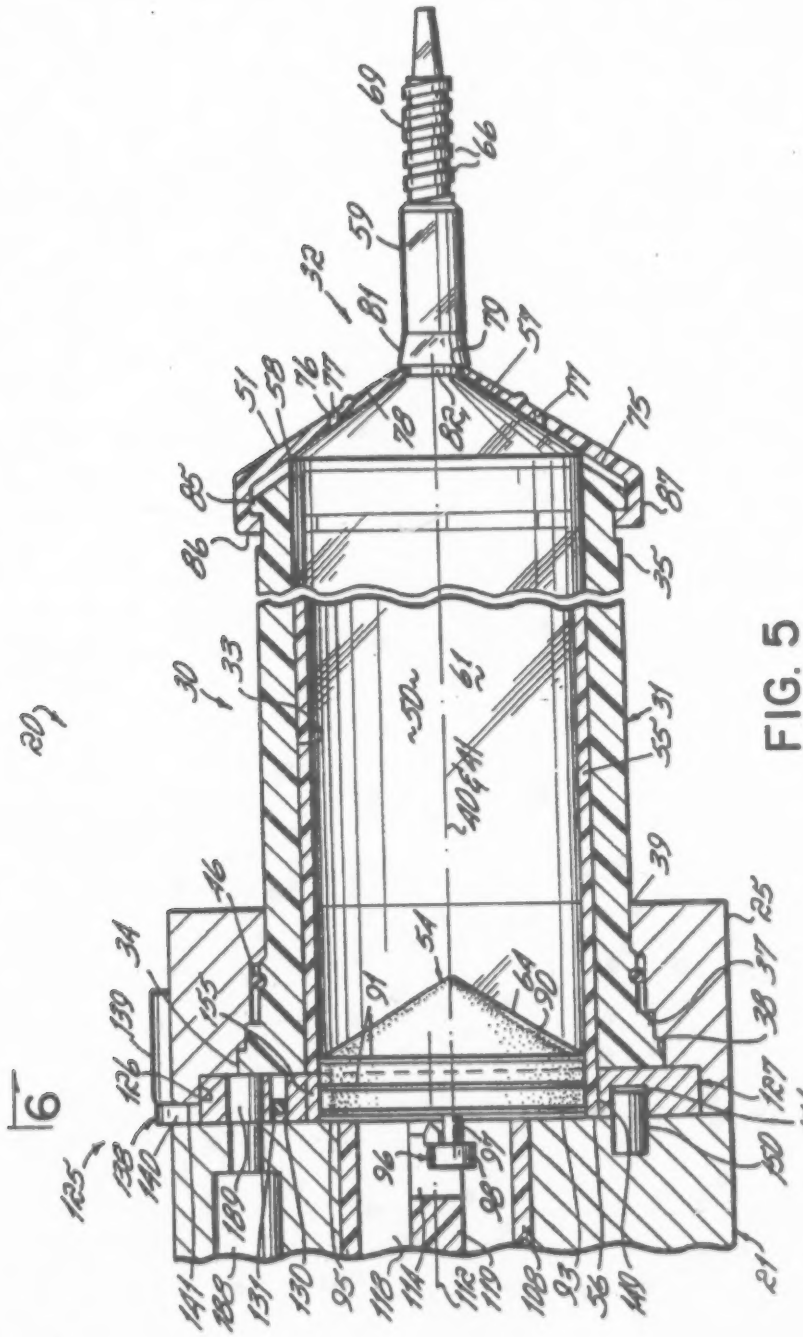

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FIG. 5

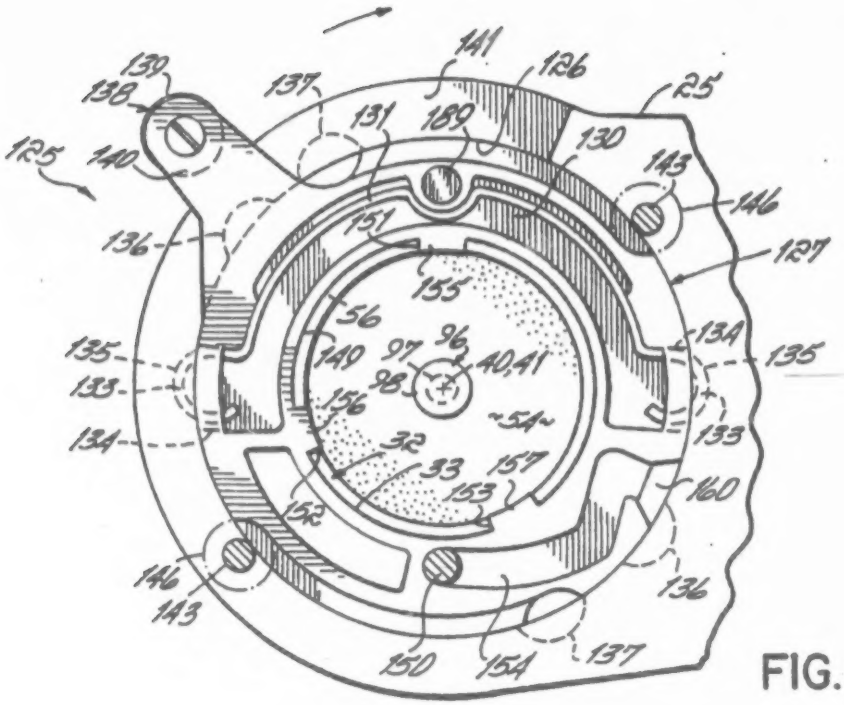


FIG. 6

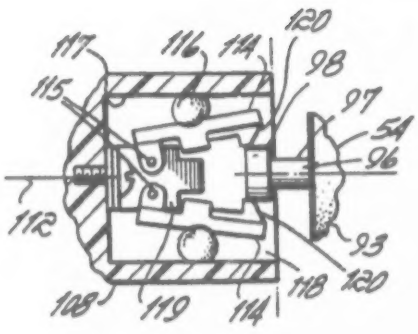


FIG. 11

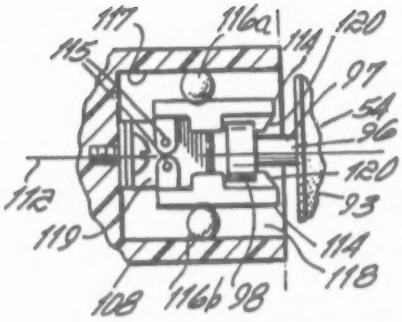


FIG. 12

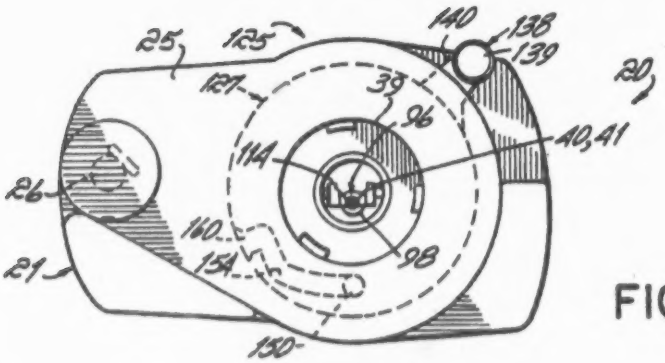


FIG. 7

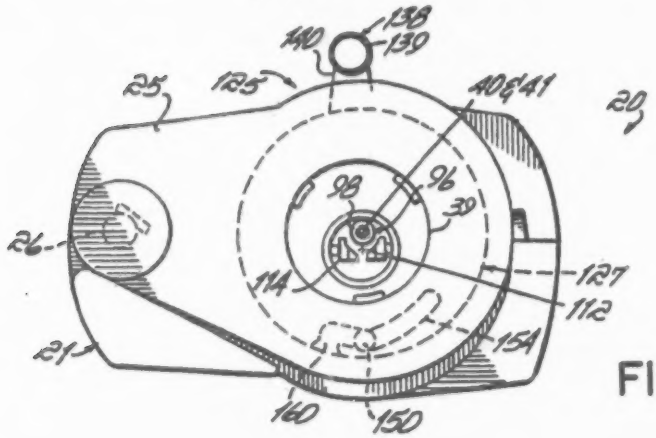


FIG. 8

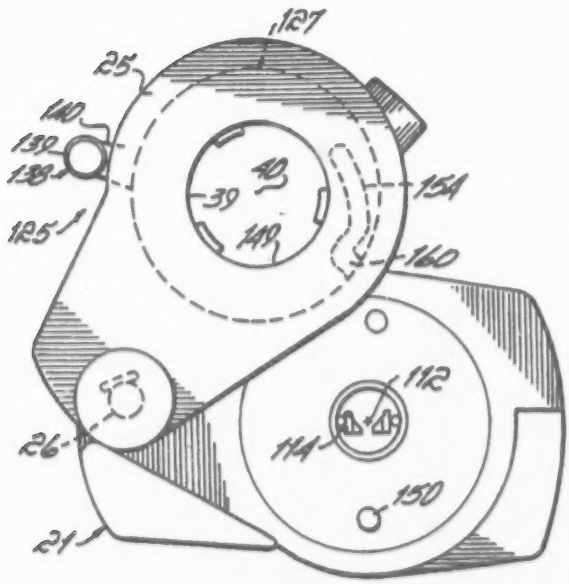


FIG. 9

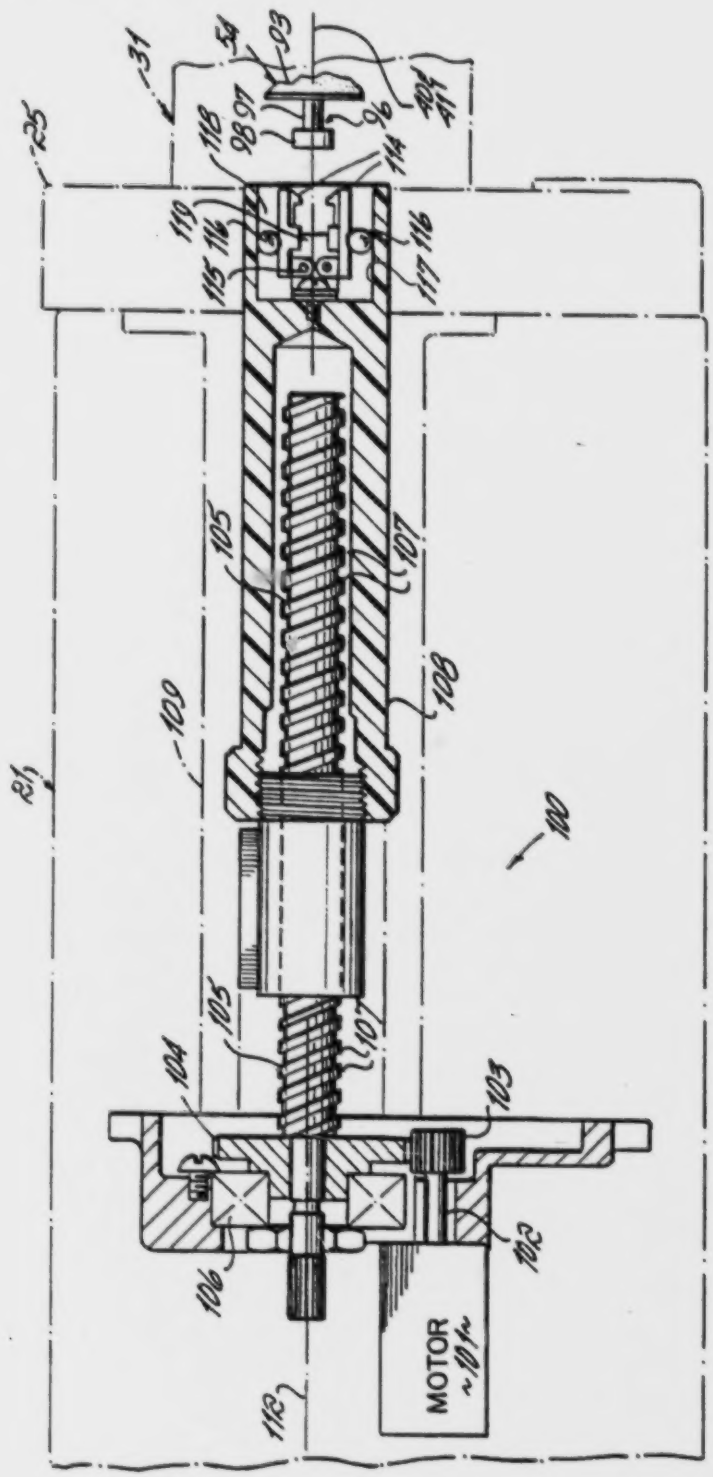


FIG. 10

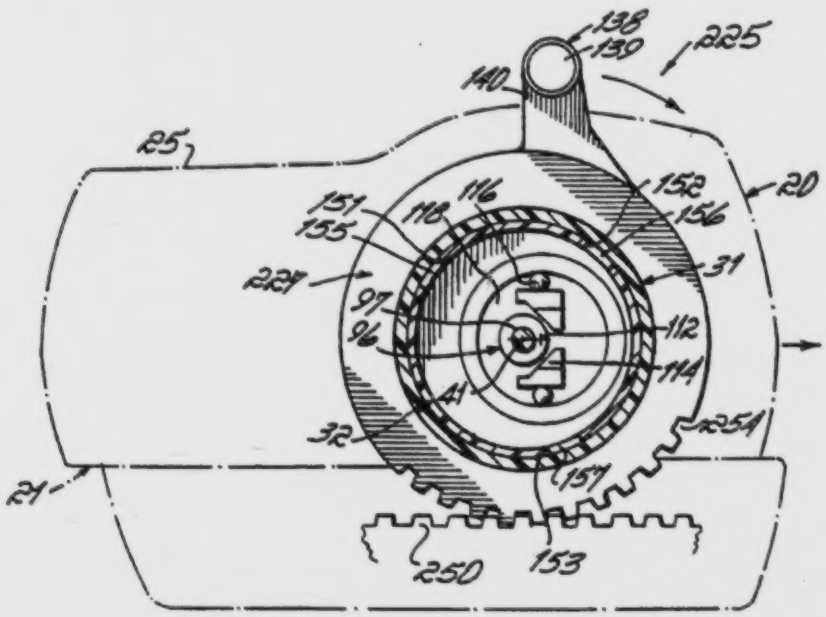

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FIG. 13

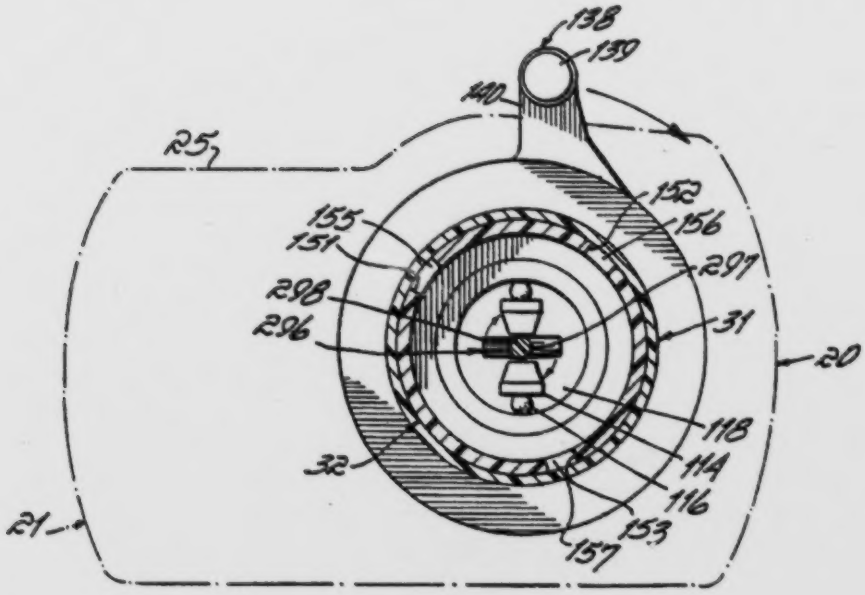

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FIG. 14

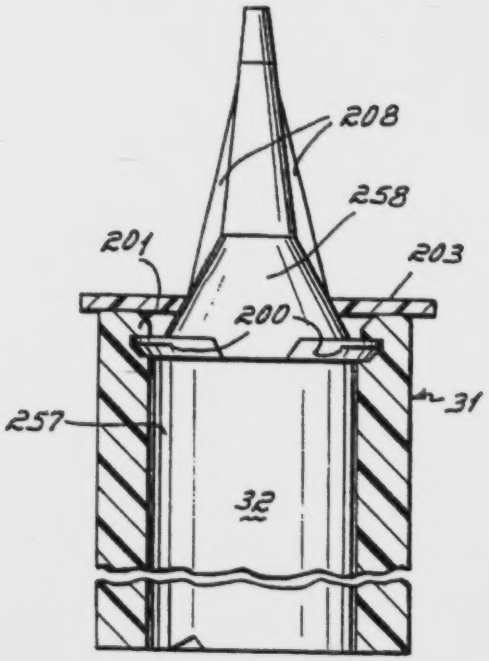


FIG. 15

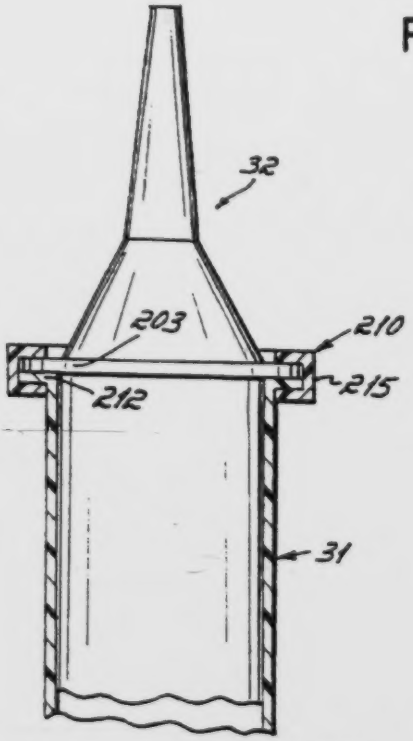


FIG. 16

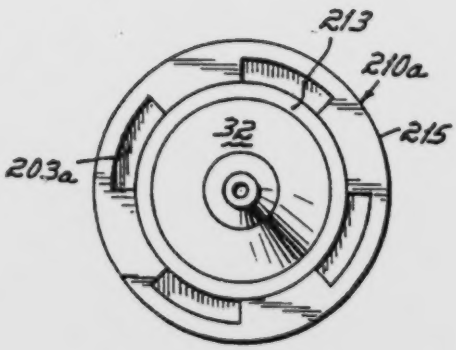


FIG. 17

METHOD OF FRONT LOADING AN INJECTOR AND INJECTING FLUID INTO ANIMALS THEREWITH

This application is a divisional of application Ser. No. 07/881,782 filed May 11, 1992, now U.S. Pat. No. 5,279,569, which is a divisional of prior application Ser. No. 07/712,110, filed Jun. 7, 1991, now U.S. Pat. No. 5,300,031.

The present invention relates to injectors and more particularly to disposable replacement syringes for animal fluid injectors.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as contrasting media, from a syringe and through a tube into an animal. The injectors are provided with an injector unit, usually adjustably fixed to a stand or support, having a drive that couples to the plunger of the syringe to drive it forward to expel fluid into the tube, or that may be driven rearward to draw fluid into the syringe to fill it. Usually the syringe is a disposable replacement type.

In the injection phase where the plunger is driven forward, pressures are developed in the syringe that range from, for example, twenty-five psi for some applications to over 1000 to 1200 psi for other applications. Syringes that will contain fluid under such pressures are expensive and therefore impractical where the syringes are to be disposable. Accordingly, many such injectors, such as angiographic injectors, for example, have been provided with pressure jackets fixed to the injector units and into which the syringes are inserted. The pressure jackets contact the outer surfaces of the syringe to restrain the walls of the syringe against the internal pressures.

To hold the syringes in the pressure jackets, the jackets of the prior art have been configured to surround the front ends of the syringes to restrain the syringe front wall against forward acting forces of the drive and the fluid pressure and to hold the syringe in the jacket. Because the front end of the pressure jacket is closed, rear loading was necessary, and accessibility thereto was provided by hinging or rotating the jacket to allow for removal and replacement of the syringe from the rear. The opening and reclosing of the injector unit to replace the syringe requires a certain amount of time, which, in the course of the procedure being performed, is not wholly desirable.

Furthermore, while for many years injector units of various types have been capable of disconnection of the plunger drive from the drive coupling on the syringe plunger at any position of the plunger within the syringe, retraction of the drive is typically required before the syringe can be removed. This is because the opening of the injector unit to remove and insert the syringe from the rear requires, for example, a translating or rotating of the jacket from the axis of the drive, which cannot be achieved if the plunger drive is extended.

For example, at the end of an injection procedure, the syringe plunger typically is forward, as is the plunger drive. Since, in the prior art injectors that load from the rear, the pressure jacket is moved through the position that the drive occupies when extended in order to remove the syringe. Hence, the syringe cannot be immediately removed without retracting the plunger drive. Further, the disposable tubing that connects to the nozzle of the syringe must be disconnected from the syringe in order to remove the syringe from the jacket. Additionally, when an empty new syringe is

inserted, the drive must be in its retracted position.

More often than not, the syringe is inserted empty and filled by retraction of the plunger with an injection tube connected to a supply of the fluid that is to be injected. In addition, before an empty new syringe can be filled, it is necessary that the plunger be fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. As a consequence of the need with such prior art injectors to retract the drive upon loading the syringe, it is then necessary to fully advance the drive to the position in which it is in engagement with the plunger and the plunger is in its full forward position. The drive then engages a coupling on the plunger of the replacement syringe. This need to retract and advance the drive contributes to a loss of time in the syringe replacement process.

Accordingly, there has been a need to more quickly load and unload disposable replacement syringes in angiographic injectors, and for injectors and replacement syringes that can accommodate a more efficient process of syringe replacement.

SUMMARY OF THE INVENTION

It is an objective of the present invention to provide a method and apparatus by which replaceable syringes can be more efficiently loaded into and unloaded from injectors.

It is a more particular objective of the present invention to provide an injector, more particularly an angiographic injector, a replacement syringe therefor, and a method of replacing the syringe in the injector that provide for more efficient replacement of the syringes in the injector. It is an additional objective of the present invention to provide an injector wherein a used syringe can be removed and a new one inserted in the injector without retraction of the drive from the pressure jacket, in most applications. It is a further objective of the invention to allow for the removal of the used syringe from the jacket without disconnection of the injector tube from the syringe nozzle.

It is still a further objective of the present invention to provide an injector, replaceable syringe and method of syringe replacement with which the replacement of the syringe can be achieved with simple motions by the operator or with rapid operation of injector unit mechanisms.

An additional objective of the present invention is to provide an injector and replaceable syringe therefor that will facilitate control of the orientation of the syringe in the jacket, and thereby provide for positive, rapid and reliable engagement of the syringe with locking structure that holds the syringe in the jacket, engagement of the plunger drive and plunger drive coupling, or connection of the injection tube to the outlet of the syringe.

A further objective of the present invention is to provide for easy to operate mechanism and reliable locking structure for locking the syringe in place in the pressure jacket of the injection unit.

Another objective of the present invention is to provide an injector and syringe arrangement that minimizes or eliminates the probability of spillage from the syringe nozzle flowing into the injector equipment, and otherwise enhancing the ability to maintain sterility and cleanliness of the equipment.

According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is

provided in the front end of the pressure jacket. To provide this front end loadable feature, the syringes of the preferred and illustrated embodiments of the present invention are provided with a front wall that is pressure restraining, that is, is of sufficient strength to support the front of the syringe against the expected pressures within the syringe, and that is securable to the front end of the pressure jacket so as to complete the pressure restraining enclosure of the syringe within the pressure jacket and hold the syringe in the jacket. In one preferred form, this front end of the injector is formed of a separate pressure restraining cap made of material that is separate from the front wall of the syringe and may be reusable. In another preferred form, the cap may be formed integrally of the front syringe wall. With the cooperating structure of the jacket and the syringe, restraining of the pressure jacket along the front and sides of the syringe is provided where the jacket allows for the replacement of the syringe from the front.

In one preferred and illustrated embodiment of the invention, the front end of the syringe locks to the front end of the pressure jacket through a cooperating engagement of mating threads on the syringe jacket. The threads include external thread sections formed at the front end of the pressure jacket and internal threads formed on an outwardly extending flange or rim of the front wall of the syringe, preferable on a pressure restraining cap. Alternatively, other securing or locking structure such as a clip or an adaptor, for example, may be employed to join the syringe to the jacket.

In the preferred embodiment of the present invention, the threads are engageable in a limited number of angular positions to thereby predetermine the angular orientation of the syringe in the pressure jacket. Additionally, other keys and keyways carried respectively by the unit and by the syringe limit the angular position in which the syringe may be inserted into the jacket to a unique predetermined angular orientation. Preferably, three keyways, such as slots or notches, unequally spaced around the back, rearward or proximate edge of the syringe body, engage similarly spaced keys or tabs on the unit at the rear end of the pressure jacket to permit insertion of the syringe into the jacket in one and only one orientation.

Further in accordance with principles of the present invention, in its preferred embodiment, a coupling on the syringe plunger is centrally located and symmetrical about the axis of the plunger. A pair of jaws on the plunger drive is moveable either by transverse straight or arcuate translatory motion or by forward longitudinal motion to form a connection between the coupling and the drive. Once coupled to the drive, the coupling remains engaged to the drive during longitudinal motion of the drive to cause the plunger to move forward or backward with the drive.

Disengagement occurs thereafter only upon transverse translational motion of the plunger with respect to the drive. In certain embodiments, this translatory transverse motion occurs by translatory movement of the jacket, and the injector unit door that carries the jacket, with respect to the plunger drive and the unit housing. In other embodiments, an asymmetrical coupling is provided that engages and disengages the plunger drive upon rotational movement of the syringe with respect to the drive.

Preferably, the motion for locking the syringe to, and unlocking the syringe from, the jacket is achieved by rotation of the syringe in the jacket, and preferably, this motion is linked to, and occurs simultaneous with, the motion that engages and disengages the plunger coupling and drive, whether that coupling is by translation or rotation. In addition, the syringe and plunger drive are so dimensioned and positioned to prevent contact between the drive and the sterile interior wall of the syringe, regardless of the position of the drive, as the syringe is being loaded.

Preferably, the syringe is formed of a cylindrical body, with the front end in the shape of a truncated cone that terminates in a forwardly extending neck with an orifice at its remote end that is connectable with an injection tube. The front end of the syringe is shaped so as to direct fluid leaking from the nozzle outwardly around the front end of the jacket. This prevents leakage, which often results upon disconnection of the injection tubing, from entering the space between the pressure jacket and the syringe body.

Replacement of the syringe begins, in the preferred embodiments of the invention, with the unlocking the syringe at its front end from the front end of the pressure jacket, preferably by rotating the syringe with respect to the jacket, and by disengaging the plunger drive from the syringe plunger, alternatively by transverse translational or rotational motion, preferably simultaneous with and linked to the motion that disengages the syringe from the jacket. The unlocking of the syringe from the jacket occurs, for example, by loosening mating threads at the front of the syringe and jacket. The twisting of the syringe in the jacket is linked to motion that either translates transversely or rotates a coupling on the syringe plunger out of engagement with the plunger drive.

Then the syringe is removed from the jacket through the open front end of the jacket. This removal may take place without retraction of the plunger drive, should the drive be advanced in the pressure jacket at the time of disengagement from the plunger coupling. The used syringe may also be removed without disconnection of the disposable injection tubing from the nozzle of the syringe.

When the used syringe is removed, a replacement syringe is inserted into the jacket through its open forward end and the front end of the new syringe is locked to the front end of the jacket, preferably by relative rotation of the syringe in the jacket to cause, for example, engagement between mating threads on the front end of the syringe and the front end of the jacket. The plunger drive, in one embodiment, is translated to bring the plunger coupling engaging jaws into alignment with the plunger coupling, preferably simultaneously with the locking of the syringe to the jacket. The jaws thereby either engage the coupling upon the translatory motion, or thereafter engage the coupling by longitudinal advancement of the drive against the coupling. In one embodiment, the jaws are positioned off center of the drive so that the drive, whether in the engaging or the disengaging positions, does not contact a syringe as the syringe is guided by the jacket during loading.

In an alternative embodiment, engagement of the plunger drive with the coupling occurs by relative rotation of the drive and the coupling, preferably by rotating the coupling relative to a stationary plunger drive, rather than by translational motion between the drive and the coupling. Only if the rest position of the plunger of the replacement syringe is behind the final position of the plunger drive at the time it was disconnected from the coupling of the plunger of the syringe being replaced need the plunger drive be retracted.

The engagement and disengagement motions between the plunger drive and plunger drive coupling, and between the syringe and the pressure jacket, are provided with manually operable mechanism that, in the preferred and illustrated embodiments, rotates the syringe in the jacket and further either rotates or translates the coupling with respect to the

plunger drive, with a simple one hand operated mechanism. The mechanism provides a convenient lever, operable through a short arc, to rotate the syringe in the jacket and to then, preferably, translate the pressure jacket that carries the syringe and is carried by the injector unit door, or to otherwise move the syringe with respect to the drive, to bring the plunger coupling of the syringe into or out of alignment with the plunger drive.

The present invention provides a disposable syringe that may be replaced in an angiographic or CT injector with great efficiency and speed. Further, replacement may occur without retraction of the plunger drive of the injector unit. Simple and rapid one hand operation of the engaging and disengaging structure is provided.

These and other objectives of the present invention will be more readily apparent from the following detailed description of the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an angiographic CT injector embodying principles of the present invention.

FIG. **1A** is a perspective view of an another form of angiographic injector embodying principles of the present invention.

FIG. **2** is an exploded perspective view of a portion of one preferred embodiment of the injector of FIG. **1**.

FIG. **3** is a perspective view of the portion of the injector of FIG. **2**.

FIG. **4** is a cross-sectional view along lines **4—4** of FIG. **3** illustrating a replaceable syringe unlocked from the housing for insertion into or removal therefrom.

FIG. **5** is a cross-sectional view similar to FIG. **4** but illustrating the syringe locked to the structure carried by the housing.

FIG. **6** is a cross-sectional view along the line **6—6** of FIG. **5**.

FIG. **7** is an elevational diagrammatic illustration of the injector of FIG. **1** with the pressure jacket and syringe removed, and showing the syringe locking structure in the locked position such as in FIGS. **5** and **6**.

FIG. **8** is an elevational diagrammatic view similar to FIG. **7** illustrating the syringe locking structure in the unlocked position such as in FIGS. **2–4**.

FIG. **9** is an elevational diagrammatic view similar to FIG. **7** illustrating the locking mechanism in the housing door release position.

FIG. **10** is a cross-sectional view through the housing of the injector taken along lines **10—10** of FIG. **1** with the plunger drive disengaged from the syringe plunger coupling.

FIG. **11** is a view of a portion of FIG. **10** illustrating the plunger drive longitudinally moving into engagement with the plunger coupling.

FIG. **12** is a view of a portion of FIG. **10** illustrating the plunger drive in engagement with the plunger coupling.

FIG. **13** is a front view of a portion of another embodiment of the injector of FIG. **1**.

FIG. **14** is a view of an alternative embodiment of a portion of a syringe according to principles of the present invention.

FIG. **15** is a cross-sectional view similar to FIG. **5** of an alternative embodiment of the invention, illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. **16** is a cross-sectional view similar to FIG. **5** of a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. **17** is a front end view of still a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. **1**, an angiographic injector **10** according to another preferred embodiment of the present invention is illustrated, configured for CT applications. The injector **10** includes a ceiling mounted support **11**, adjacent a CT X-ray unit, to the lower surface of which is rigidly supported a vertically descending support column **12**.

Remote from the support **11** is an injector control module console **13** behind a wall which isolates the operator area from the X-ray equipment. The console **13** is located adjacent a control **14** of the X-ray equipment. Electrical power and control cables (not shown) communicate power and control signals through the support **11** and the column **12** and to a power lead **15**. The console **13** connects with an injector control module **16**, which includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard **17** on the console **13**. The console **13** is also provided with an operator display **18** to aid in interfacing the input commands and injector status with the operator.

Attached to the column **12** is an articulating adjustable arm **19**. To the remote end of the arm **19** is adjustably supported injection module unit **20**. The arm **19** is capable of setting the unit **20** at varying positions adjacent a patient bed of the CT unit.

Referring to FIG. **1A**, an angiographic injector **10***a* according to another preferred embodiment of the present invention is illustrated. The injector **10***a* includes a wheeled base **11***a* to the top of which is rigidly supported a vertically adjustable upstanding support column **12***a*. To the top of the column **12***a* is supported a control module platform **13***a*. Electrical power is communicated from a power cord (not shown) through the base **11** and the upstanding support **12***a* and through a power lead **15***a* to a control module **16***a* rigidly supported to the platform **13***a*. The control module **16***a* includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard **17***a* on the module **16***a*. The module **16***a* is also provided with an operator display **18***a* to aid in interfacing the input commands and injector status with the operator. Attached to the platform **13***a* is an articulating adjustable arm **19***a*. To the remote end of the arm **19***a* is adjustably supported the injection module unit **20**.

The injection module unit **20** of the embodiments of FIGS. **1** and **1A** includes a housing **21** which contains the operating drive structure of the injector **10** or **10***a*. The housing **21** has a support bracket **23** fixed thereto and adjustably pivotally supported to the remote end **24** of the articulating arm **19** or **19***a*. The housing **21** has pivotally attached to the front thereof a door **25** at the front thereof which is pivotally connected to the housing **21** at a longitudinally extending pivot or hinge pin **26** (FIG. **2**) rigidly supported on the housing **21** and extending forwardly from the front of the housing **21**.

On the top of the housing **21** is an injector position and local control panel **27** having a position indicator scale **28**

thereon, which displays the position of the injector drive to the operator. The panel **27** also includes a pair of forward and reverse drive direction control buttons **29**, which are selectively actuatable to activate a drive within the housing **21** in either the forward or reverse directions.

Extending forwardly from the front of the door **25** is an injector syringe and pressure jacket assembly **30**, the structure of which can be better understood with reference to FIGS. 2–5 below. The syringe and jacket assembly **30** includes a hard plastic pressure jacket **31**, which may be of opaque or transparent material, a removable and replaceable disposable syringe **32**, which may be of opaque, transparent or semi-transparent material, and related structure hereinafter described.

The syringe **32** is disposable, and includes walls which will withstand only moderate or low pressure. The walls are usually outwardly deformable under operating pressures, particularly pressures of 300 psi or more. Such higher pressures are necessary to overcome pressure drops through the injection tubing at higher flow rates, which are often desirable. The jacket **31** is made of a stronger transparent material that will withstand the operating pressures. When the syringe **32** is contained in the jacket **31**, it is surrounded by the jacket **31** and supported by the jacket **31** against expansion caused by the fluid pressure within as the syringe **32** expands against the jacket wall.

The pressure jacket **31** has a generally cylindrical inner bore **33** extending therethrough from a proximate end **34** adjacent the door **25** to a remote end **35** of the pressure jacket **31** toward the front of the unit **20**. The bore **33** is dimensioned so as to receive through the remote end **35** the disposable syringe **32** and to support the syringe against expansion from fluid pressure within such fluid pressure may range to more than a thousand psi. The pressure jacket **31** has an annular flange **37** extending outwardly around the proximate end **34**. The flange **37** is integrally formed with the jacket cylinder and is shaped to conform to an annular recess **38** surrounding a circular hole **39** in the door **25** to which the jacket **31** may be assembled by insertion from the rear. The hole or opening **39** in the door **25** and the cylindrical bore **33** of the jacket **31** are concentric with a longitudinal axis **40** on which also lies an axis **41** of the syringe **32** when the syringe **32** is positioned in the bore **33** of the jacket **31**. The jacket **31** is firmly and rigidly attached to the door **25** with a pair of screws **43**, only one of which is shown, which are threaded into a pair of holes **44** in the back of the door **25** (FIG. **2**). An O-ring seal **46** surrounds the flange **37** of the jacket **31** in the recess **38** of the door **25**.

The syringe **32** includes a syringe case **50** formed of a single piece of molded plastic material, a pressure cap **51**, a tubing collar **52** (FIG. 3) and a plunger **54** (FIGS. 3–5). The syringe case **50** includes a cylindrical syringe body **55** having an open proximate end **56** and a remote end **58** to which is integrally formed a conical front wall **57**. The front wall **57** is truncated at its forward end, to which is integrally formed an elongated neck **59** extending from the wall **57** at the center thereof. The neck **59** of the syringe case **50** has an orifice **60** (FIG. 3) in its remote end which communicates with an internal syringe cavity **61** formed within the neck **59**, the conical front wall **57** and the cylindrical body **55** of the case **50** of the syringe **32**. The rear end of the cavity **61** is further defined by a forward facing conical surface **64** of the plunger **54**. The conical surface **64** is of a slope which conforms to the slope of the interior of the conical front wall **57**. The plunger **54** is slidable within the body **55** of the syringe case **50** such that the cavity **61** is of variable volume.

Near the front end of the neck **59** of the syringe case **50**, just behind the orifice **60**, is an external thread **66** configured to mate with threads **67** on the interior of collar **52** (FIG. 3). The thread **66** in the neck **59** has an stop **69** at near forward end thereof to engage an abrupt step **70** on the thread **67** of the collar **52** so that, when the syringe **32** is properly oriented in the jacket **31**, the collar **52**, when loosened to its maximum extent, will assume a predetermined orientation so as to present, in an upwardly facing orientation, a tube end receiving slot **62** formed in the remote end of the collar **52**. This slot **62** is of T-shaped cross-section so as to receive the enlarged flange end **63** of a tube **65** through which fluid from the syringe cavity **61** is injected into a patient.

The cap **51** is generally conical in shape and has an inner rearward surface **75**, which conforms to the front surface of the conical wall **57** of the case **50** of the syringe **32**. In certain embodiments, the rearward conical surface **75** of the cap **51** may be bonded to the front surface of the conical wall **57** of the case **50** of the syringe **32**, or it may be formed integrally therewith, molded from the same plastic material as the case **50** of the syringe **32**. In the preferred and illustrated embodiment, the cap **51** is separate from the syringe body portion **55** and has a pair of holes or detents **76** into which fit a pair of projections **77** extending forwardly from and formed integrally on the outer surface of the conical wall **57** of the case **50** of the syringe **32**. The cooperation of the pins or projections **77** with the holes or detents **76** prevent the cap from rotating with respect to the syringe case **50** when the cap **51** is mounted on the syringe **32**.

To hold the cap **51** against the conical wall **57** of the case **50** of the syringe **32**, six resilient tabs **78** are formed about a central inner hole **79** of the cap **51**. The tabs **78** are separated by six equally spaced radial slots **80** (FIG. 3). The hole **79** in the cap **51** is equal to or only slightly greater in size than the circular forward end of the conical wall **57** of the case **50** of the syringe **32**. The neck **59** of the syringe **32** has an enlarged straight section **81** slightly greater in diameter than the hole **79** in the cap **51** and also greater in diameter than the forward end of the conical wall **57** of the case **50**, thereby forming a groove **82** at the juncture of the straight neck portion **81** with the conical wall **57** so that the tips of the tabs **78**, which are sufficiently resilient to slide over the enlarged neck portion **81** as the cap **51** is inserted on the case **50** of the syringe **32** with the hole **79** surrounding the neck **59** to snap fit into the groove **82**.

The syringe **32** includes structure that is configured to lock the syringe **32** to the front end of the jacket **31** by cooperating with mating structure on the jacket **31**. The jacket **31** has, spaced around the circumference thereof near the remote or front end **35** of the jacket **31**, four equally spaced outwardly projecting thread sections **85**. These thread sections **85** are slightly less than 45° in extension around the circumference of the jacket **31** and are spaced apart with gaps of slightly greater than 45°. The cap **51** has a cylindrical rim **87** in which are formed four similarly sized and spaced mating thread sections **86**. The thread sections **86** project inwardly toward the jacket **31** when the syringe **32** is positioned in the jacket **31**. As such, when the syringe **32**, with the cap **51** assembled to it is inserted into the jacket **31**, the threads **86** of the cap **51** pass through the spaces between the threads **85** on the jacket **31** to a point behind the threads **85**. When so inserted, the syringe assembly **32** with the cap **51** may be twisted clockwise 45° to tighten and thereby secure the cap **51** to the jacket **31** by engagement between the threads **85** and **86** as shown in FIG. 5, to thereby lock the syringe in the bore **33**.

The piston **54** of the syringe **32** is molded of an elastomeric material. Preferably, the piston **54** includes two por-

tions molded of different materials and bonded together. These portions include a forward more flexible portion **90** in which is formed the forward conical surface **34**. This forward portion **90** has a pair of outwardly extending rings **91** formed in the periphery thereof to make sealing engagement with the inside of the wall of the cylindrical body **55** of the syringe case **50**. The rearward portion of the piston **54** is a flat circular surface to which is bonded the flat circular forward surface of a more rigid rear portion **93** of the piston **54**. The rear rigid portion **93** of the piston **54** is molded of a harder stronger plastic material and has a rearward facing circular surface **95** having a rearward extending coupling **96** integrally formed thereon at its center. The coupling **96** includes a rearwardly extending cylindrical shaft **97** on the axis **41** of the syringe **32** and a larger symmetrical cylindrical button **98** integrally formed at the rear end of the cylindrical shaft **97**.

Referring to FIG. **10**, a piston drive assembly **100** is illustrated contained within the housing **21**. The drive assembly **100** includes an electric motor **101** mounted within the fixed housing **21** and having a rotary output shaft **102** with a drive gear **103** fixed to the remote end thereof. The drive gear **103** is positioned for driving engagement with a driven gear **104** fixed near the rear end of a drive screw or shaft **105** supported at its rear end in a bearing **106** fixed in the housing **21**. The screw or shaft **105** has a continuous external helical thread **107** thereon which mates with interior threads of a carriage **108**. The carriage **108** is slidably supported in a bushing **109** fixed in the housing **21**. The shaft **105** rotates within the housing **21** about a longitudinal axis **112**.

At the forward end of the carriage **108** is supported a pair of hooked jaws **114** which are pivotally mounted at their rearward ends by a pair of pivot pins **115** to the carriage **108**. The jaws **114** are biased toward the axis **112** by a pair of balls **116***a* and **116***b* of resilient material positioned between the outside of the jaws **114** and an inner cylindrical wall **117** of a recess **118** formed in the forward end of the carriage **108**. The balls **116***a*, **116***b* are partially captured in depressions in the outer surfaces of the jaws **114**. The balls **116***a*, **116***b* bias the jaws toward their innermost position toward the axis **112**. The innermost position of the jaws is determined by a spacing block **119** on the axis **112** of the carriage **108** at the center of the cavity **118**.

When a syringe **32** is locked in the jacket **31** with its axis **41** and the axis **40** of the jacket **31** may be in alignment with the axis **112** of the shaft **105**, the plunger **54** may be located in the cylindrical body **55** of the syringe case **50** in a position forward of the remote end **56**. Preferably, however, the jaws **114** are displaced to the side of axis **112** of the shaft **105** so that as the jaws **114** and coupling tip **98** are in their disengagement position, maximum clearance is provided so that the syringe **32** may be inserted into the jacket **31** without the sterile internal walls of the syringe **31** touching the components of the drive, as illustrated in the figures.

In the engaging position, the jaws **114** are nonetheless in alignment with the coupling **98** on the axes **40** and **41** of the jacket **32** and syringe **32**. In such a situation, the jaws **114** may be in a retracted position at the center of the opening **39** of the door **25** adjacent to the proximate end **34** of the jacket **31**, and out of engagement with the coupling **96** on the plunger **54**. From this position, operation of the motor **101** rotates the shaft **105** and drives the carriage **108** forwardly to move the jaws **114** toward and into engagement with the coupling **96** on the plunger **54**. This engagement takes place as shown in FIG. **11** where a pair of tapered cam surfaces **120** at the forward interface of the tips of the jaws **114** engage the enlarged portion or button **98** of the coupling **96** to expand the jaws, as shown in FIG. **11**, to snap around the button **98** of the coupling **96** to form a driving engagement between the drive assembly **100** and the coupling **96** of the plunger **54** as shown in FIG. **12**. Once so engaged, any forward or reverse movement of the carriage **108** under the power of the motor **101** will cause the plunger **54** to be driven either forwardly or backwardly in the syringe body **55**.

Disengagement of the jaws **114** from the coupling **96** can thereafter be achieved by translational movement between the coupling **96** and the jaws **114** between a disengaged position as shown in FIG. **4** and an engaged position as shown in FIG. **5**. When the plunger coupling **96** and the jaws **114** are disengaged, the syringe **32** can be replaced without the need to retract the carriage **108** of the drive **100**. This allows for rapid replacement of the syringe **32**. Preferably, the jaws **114** are either fully retracted toward the housing **21** where engagement by translation of the coupling **96** will occur, or the jaws **114** are sufficiently within the jacket prior to replacement of the syringe so that the coupling **96** of the replacement syringe **32** will not contact the jaws **114** except as the drive **100** is advanced.

If sterility is not a problem, the most time saving approach would be to insert the syringe **32** into the jacket **31** with its plunger all the way forward and the drive fully advanced so that, when the syringe is translated toward the jaws **114**, engagement will immediately occur and the plunger can be immediately retracted to fill the syringe.

When a syringe **32** is inserted into the jacket **31** when the plunger **54** is at its rearmost position toward the proximate end **56** of the syringe body **55**, the coupling **96** is in a position adjacent the proximate end **56** of the syringe body **55** and projecting rearwardly therebeyond. When in such a position, engagement between the jaws **114** and the coupling **96** is brought about by translational movement between the position shown in FIG. **4** and that shown in FIG. **5**. In the unlocked or disengaged position shown in FIG. **4**, the axes **40** and **41** of the jacket **31** and the syringe **32**, respectively, as well as the center of the opening **39** of the door **25**, lie spaced from and parallel to the axis **112** of the shaft **105** as shown in FIG. **4**. In the locked or engaged position, the axis **112** of the shaft **105** is slightly eccentric relative to the axes **40** and **41** of the jacket **31** and syringe **32**, respectively, as shown in FIG. **5**. This translational movement, the engagement and disengagement between the coupling **96** and the jaws **114** and the 45° rotational movement which secures the cap **51** to the pressure jacket **31** by engagement of the threads **85** and **86** are brought about by operation of a translating and locking mechanism **125**, which is best understood by reference to FIGS. **2–9**.

The translating and locking mechanism **125** includes a cam and locking ring **127** which is rotatably retained in a circular recess **126** in the back of the door **25**. The ring **127** has a generally semi-circular groove **130** in the back surface thereof for receiving a spring wire retaining clip **131** having a pair of looped ends **133** which extend through a pair of slots **134** in the rim of the ring **127** and into a selected one of three pair of diametrically opposed notches **135**, **136** and **137** in the inner wall of the rim of the recess **126** in the door **25**. The three pair of notches **135**, **136** and **137** represent three positions of the translating and locking mechanism **125** which are the locked, unlocked and release positions, respectively. The locked position of the mechanism **125** in which the loops **133** of the ring **131** are in the notches **135**, is that illustrated in FIGS. **5–7** and **10**. The unlocked position, in which the loops **133** of the ring **131** are in the

notches 136, is that illustrated in FIGS. 2–4 and 8. The release position, in which the loops 135 of the clip 133 are in notches 137, is that illustrated in FIG. 9. The ring 127 is moved among these three positions by a manually accessible handle 138 in the form of a cylindrical knob 139 rotatably attached to a lever arm 140 formed integrally and extending radially from the ring 127 through a slot 141 in the door 25 (FIG. 1). The ring 127 is retained in the recess 126 by a pair of screws 143 which thread into countersunk holes 144 at the periphery of the recess 126 in the back of the door 25. These screws 143 have enlarged heads 146, which, when seated in the holes 144, overlie the edge of the ring 127, thereby securing it for rotatable movement within the recess 126.

As shown in FIGS. 2 and 6, the ring 127 has an inner periphery 149 which is larger than the circumference of the body 55 of the syringe case 50. Accordingly, when the syringe 32 is inserted in the jacket 31, the proximate end 56 of the syringe case 50 extends through and is surrounded by the inner periphery 149 of the ring 127. Asymmetric keyway structure, preferably in the form of three slots or notches 151, 152 and 153 (FIG. 6) are provided in the edge of the proximate end 56 of the body 55 of the syringe case 50. The spacings between adjacent pairs of the notches 151–153 differ from each other. Formed integrally of the ring 127 and projecting inwardly from the inner periphery 149 thereof are three tabs or keys 155, 156 and 157. These tabs 155–157 are spaced so as to fit into the respective notches 151–153 in the proximate end 56 of the body 55 of the syringe case 50 so as to rotate the syringe 32 as the mechanism 125 is rotated through actuation of the handle 138. Because the notches 151–153 and the tabs 155–157 are unequally spaced, they can only engage each other when the syringe 32 is inserted into the jacket 31 in one and only one orientation. That orientation is one which will cause the slot 62 of the collar 52 (FIG. 3) to align 45° counterclockwise of the vertical when the mechanism 125 is in its unlocked position, which is a position in which it will be when the syringe is first inserted into the jacket 31, and to be in an upwardly facing orientation, when fully loosened, when the mechanism 125 is moved to its locked position. Accordingly, the notches 135 and 136 in the recess 126, which receive the loops 133 of the spring clip 131 when respectively in the locked and unlocked positions, are 45° apart.

The rotation of the mechanism 125 from the unlocked position to the locked position rotates the syringe 32 in the jacket 31 and rotates the cap such that its threads move from an unlocked position as shown in FIG. 4 to the locked position of FIG. 5, to secure the cap to the jacket 31 by the engagement and tightening of the threads 85 and 86.

The translational movement of the axes 40 and 41 with respect to the axis 112 is achieved by a fixed cylindrical cam follower or pin 150 which projects outwardly from the fixed housing portion 22 behind the ring 127 and into a cam slot 154 formed therein. The slot 154 is shaped so that the axes 40 and 41 which remain fixed with respect to the ring 127, along with the door 25, the jacket 31, the syringe 32 and all of the structure mutually carried thereby, are moved in relation to the axis 112 of the shaft 105 and the other structure mutually carried by the housing 22, as the mechanism 125 is rotated. These axes move toward and away from each other in accordance with the shape of the slot 154 determined by the radial distance from the point along the slot 154 where it engages the pin 150 to the axes 40 and 41.

The cam slot 154 in the ring 127 is shaped such that, when the mechanism 125 is in the locked position as shown, for example, in FIGS. 6 and 7, the distance between the pin 150 and the axes 40 and 41 is at a minimum and the axis 112 coincides with the axes 40 and 41. This is illustrated in FIGS. 5 and 7 wherein the coupling 96 is shown positioned between the jaws 114 and in mutual engagement therewith. When the mechanism 125 is in the unlocked position, with the loops 133 of clip 131 in the notches 135 (FIG. 6) of the recess 126, the pin 150 lies in the slot 154 in the position shown in FIG. 8, which is farther displaced from the axes 40 and 41 than in the position of FIGS. 6 and 7, so that the coupling 96 is translated to a position outside of the center line of the jaws 114, as shown in FIG. 8 and further illustrated in FIG. 4.

In the release position, as shown in FIG. 9, the pin 150 is positioned at the open end 160 of the cam surface of the slot 154 so that the door 25 can be rotated upwardly about the hinge pin 26, as shown in FIG. 9, to open the space behind the door 25 for access thereto. This position may be used for cleaning the area behind the door 25 which is sometimes necessary because of possible leakage of fluid from the cavity 61 into the space behind the plunger 54. This can possibly occur because the fluid within the cavity 61, when being injected by forward advancement of the plunger 54, may be of relatively high pressure in the range, usually over 200 psi. For applications such as the injection of contrasting fluid for CT scanning, pressure may typically be in the range of from 25 to 300 psi., while in some angiographic injection applications the pressure may range to 1200 psi or higher.

In addition, leakage rearwardly along the exterior of the neck 59 of the syringe 32 can cause fluid to flow between the body portion 55 of the syringe 32 and the jacket 31. For this reason, the cap 51 is caused to fit snugly against the forward surface of the conical portion 57 of the syringe 32 at least sufficiently to restrict the flow of this leaking fluid onto the neck 59. This is assisted by the configuration of the cap 51 at the rim 87 thereof so as to divert away from the space between the syringe 32 and jacket 31 fluid which might leak from the nozzle.

The front of the housing 21 has formed thereon a door stop 185 having a slot 186 formed therein for receiving a lug 187 of the door 25, to restrain the door 25 against forward force exerted by the drive 100. Behind the front of the housing 21 adjacent the stop 185 is a magnetic sensor 188, which is responsive to the presence of a magnet 189 in the lever arm 139 of the handle 138. The sensor 188 generates a signal to the control module 16 to activate the drive 100 only when the mechanism 125 is in its locked position.

Referring to FIG. 13, there is illustrated a locking mechanism 225 that is an alternative to the locking mechanism 125 described above. In the locking mechanism 225, a stationary geared rack 250 is provided fixed to the housing 21. A mating gear segment 254 is formed on the outer rim of the alternative locking ring 227 of this embodiment. The gear segment 254 and rack 250 replace and function in the same way as the slot 154 and pin 150 of the embodiment described above. As the mechanism 225 is rotated by the handle 138, the door 25 that carries the jacket 31 and the syringe 32 is translated to bring the coupling 96 into or out of engagement with the jaws 114 of the drive 100. Simultaneous with this translatory motion, the syringe 32 is rotated in the jacket 31 to lock or unlock the syringe 32 to the jacket 31 by engagement or disengagement of the threads 86 on the syringe 32 with the threads 85 on the jacket 32.

FIG. 14 illustrates an alternative to the embodiment of the coupling 96 described above. In the embodiment of FIG. 14, there is provided a coupling 296 that is T-shaped, having a rectangular endpiece 298 at the rearward end of a cylindrical or square shaft 297 on the rearwardly facing circular surface

95 of the plunger 54. Such a coupling 296 engages the jaws 114 by rotation of the locking mechanism 125 or 225, preferably through an angle of 90°. When the orientation of the endpiece 298 is parallel to the plane of the jaws 114, the drive 100 is locked to the plunger 54 so that axial movement of the drive 100 moves the plunger axially, in the forward direction to expel fluid form the syringe cavity 61, or in a rearward direction to fill the cavity 61 with fluid. When the endpiece 298 is perpendicular to the plane of the jaws 114, the coupling 296 will move into or out of engagement with the jaws 114 upon relative axial movement between the plunger 54 and the drive 100. Thus, with this embodiment, rotational motion, rather than translational motion, causes engagement and disengagement of the coupling 296 by the jaws 114. With this embodiment, orientation of the syringe 32, when loaded into the jacket 31, is preferably maintained through the cooperation of the notches 151–153 and the tabs 154–156 (FIG. 4), so that the coupling 296 will enter the jaws 114, when the syringe 32 is inserted into the jacket 31, with the endpiece 298 perpendicular to the pair of jaws 114.

The locking structure between the syringe 32 and the pressure jacket 31 should provide for retention of the syringe 32 in the jacket 31 against the force of the fluid pressure in the cavity 61 or axial force otherwise exerted on the plunger 54 by the drive 100. This locking of the syringe 32 to the jacket 31 is preferably achieved, as shown in FIG. 5, by structure at or near the forward wall 57 of the syringe case 50. In accordance with the embodiment of FIG. 15, such structure may include external threads 200 on the forward end of the syringe body 257, which mate with internal threads 201 at the remote end of the jacket 31. With such an embodiment, the syringe 32 is preferably provided with an annular flange 203 around the body 257 at the juncture of the body 257 with the syringe front wall 258. The flange 203 inhibits the flow of leaked fluid into the space between the syringe body 257 and the jacket 31. With such an embodiment, the wall 258 is either thickened, provided with reinforcing such as the ribs 208, or provided with other structure to resist deformation of the wall 258 under the pressure of the fluid within the cavity 61.

Alternatively, a reusable split clip 210 may be employed to secure a continuous flange 203 of such a syringe to a continuous flange 212 at the end of the pressure jacket in the embodiment of FIGS. 16. As a further alternative as shown in FIG. 17, a ring clip 210a having an outer rim 215 and rotatably mounted to the syringe 31, encircles and engages outwardly projecting threads of a disk flange 213 formed at the front end of the jacket 31, as the syringe 32 is twisted onto the jacket 31, to engage the jacket in a manner similar to the threads 85 and 86 in the embodiment of FIGS. 2–12 above.

The invention has been described in the context of its preferred embodiments. It will be appreciated by those skilled in the art that variations and alternatives to the embodiments described may be employed without departing from the principles of the present invention. Accordingly, this patent is not intended to be limited except by the scope of the following claims:

We claim:

1. A method of loading an empty syringe into a power injector for injecting fluid into an animal and for filling the syringe with the fluid to be so injected, wherein the injector has a syringe receiving opening therein and a power driven ram extendable through the opening, the method comprising the steps of:

providing adjacent the opening an empty syringe having a tubular body having a hollow interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger moveable in the hollow interior between the rearward end and forward end, the plunger being in an initial position proximate the forward end;

translating the rearward end of the syringe longitudinally rearwardly from adjacent the opening toward and into the opening to load the injector with the syringe;

locking the syringe when in the opening to the injector;

providing the ram in a forward position extending through the opening and the rearward end of the body of the syringe and into the hollow interior of the syringe;

coupling the ram in the interior of the syringe to the plunger;

connecting a supply of fluid to the discharge orifice;

energizing a ram drive to translate the coupled ram rearwardly from the forward position to thereby move the plunger rearwardly in the body to draw fluid into the interior of the syringe through the orifice from the connected supply.

2. The method of claim 1 further comprising the steps of:

after drawing fluid into the interior of the syringe body, disconnecting the supply from the orifice; then,

connecting a tube between the orifice and the animal; then,

energizing the ram drive to translate the ram forwardly in a programmed motion to thereby translate the plunger forwardly to inject a programmed flow of fluid from the hollow interior, through the orifice and into the cardiovascular system of the animal.

3. The method of claim 1 wherein:

the ram is provided in the forward position before the rearward end of the syringe is translated longitudinally rearwardly whereby the ram extends through the opening into the hollow interior of the syringe.

4. The method of claim 1 wherein:

the syringe locking step and the ram coupling step are performed simultaneously.

5. The method of claim 1 wherein:

the syringe locking step and the ram coupling step are both carried out by rotating the syringe.

6. A method of loading a syringe into an injector, where the syringe has a hollow tubular body enclosing an interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger slidable within the body, and the injector has a power driven ram for moving the plunger of the syringe, when loaded on the injector, longitudinally in the body to inject fluid into an animal the method comprising the steps of:

positioning the syringe adjacent the injector and, with the ram extended toward the syringe, moving the body of the syringe rearwardly toward the injector so that the ram enters through the open rearward end of the syringe and into the interior;

while rearwardly moving the syringe, guiding, with structure supported on the injector, the body of the syringe so as to maintain the body out of contact with the ram;

connecting the body of the syringe to the injector;

coupling the plunger to the ram; and

applying power to the ram and therewith retracting the ram toward the injector to thereby rearwardly slide the plunger in the body and thereby fill the syringe with

fluid drawn through the orifice.

7. The method of claim 6 further comprising the steps of:

connecting the orifice through a tube to the animal;

applying additional power to the ram to translate the ram forward at a programmed speed and thereby translate the plunger forwardly at the programmed speed to inject the fluid from the filled syringe, through the orifice and through the tube at a programmed rate into the body of the animal.

8. The method of claim 6 wherein:

the syringe body connecting step and the plunger coupling step are performed simultaneously.

9. The method of claim 6 wherein:

the syringe body connecting step and the ram coupling step are both carried out by rotating the syringe body relative to the injector.

10. A method of loading a tubular replacement syringe into a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:

providing a power injector having:

a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim,

a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening; and providing a hollow tubular syringe that includes:

a cylindrical body having an axis, a generally circular rim, a rearward end and a closed forward end with a fluid discharge orifice therein, and

a plunger axially slidable in the body, the syringe body being structurally capable of withstanding, at least from the rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

then:

inserting into the opening, by generally rearward axial movement of the syringe, the rearward end of the body;

rotating the syringe in the opening a fraction of a turn to thereby lock the body around the rim to the injector around the periphery of the opening; and

engaging the plunger with the ram;

then:

energizing the motor and thereby driving the ram forward along the line and parallel to the axis to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure from within the syringe and through the orifice at a programmed rate into the animal.

11. The method of claim 10 further comprising the steps of:

providing a cooperating coupling elements on the ram and the plunger for releasably coupling the ram and the plunger;

providing linkage interrelating rotation of the syringe relative to the injector and movement of the coupling elements relative to each other;

imparting to the syringe a releasing motion to rotate the syringe relative to the opening and thereby unlock the syringe from the injector and to uncouple the plunger from the ram; and

removing the syringe from the injector by generally forward axial movement of the syringe from the opening.

12. The method of claim 11 wherein:

the motion imparting step includes the step of translating the plunger transversely relative to the ram to uncouple the plunger from the ram in a motion linked to the rotation of the syringe relative to the opening.

13. The method of claim 10 wherein:

the step of locking of the syringe body to the injector includes the step of threading the rim around the opening.

14. The method of claim 10 wherein:

the injector includes a hollow pressure jacket projecting therefrom having an open front end, the opening being located at the front end of the pressure jacket, the jacket having an internal cross-section dimensioned to surround and provide pressure restraining exterior support to the body of a syringe, inserted in the jacket through the opening, between at least the rearward end of the body to the rim;

the peripheral rim of the syringe is located at the forward end thereof;

the syringe inserting step includes the step of translating the syringe rearwardly and inserting thereby the body of the syringe, from the rearward end to the rim, into the jacket; and

the rotating step includes the step of locking the forward end of the syringe to the front end of the jacket.

15. The method of claim 14 wherein:

the plunger engaging step occurs upon the performance of the syringe rotating step.

16. The method of claim 10 wherein:

the syringe rotating step and the plunger engaging step are performed simultaneously.

17. The method of claim 10 wherein:

the engaging of the plunger with the ram occurs upon the performance of the syringe rotating step.

18. The method of claim 10 further comprising the step of:

after engaging the plunger with the ram and before the step of energizing the motor and thereby driving the ram forward, retracting the ram and thereby rearwardly moving the plunger and thereby drawing fluid into the syringe through the orifice.

19. A method of removing a disposable syringe from a power injector after injecting fluid into an animal therewith, the injector having a powered ram extendable from the front end thereof, the method comprising the step of:

providing the injector having an opening at the front end of the injector dimensioned to receive the back end of a disposable syringe therein such that the ram is extendable into an open rearward end of a syringe inserted in the opening;

providing the disposable syringe having an open rearward end inserted in the opening and locked to the injector, the syringe further having a hollow body, a plunger slidably mounted in the body and coupled to the ram of the injector, and a closed forward end having an orifice therein;

providing fluid in the hollow interior of the syringe;

providing a tube connected between the and the animal;

then:

driving the ram forward to move the plunger axially forward at a programmed speed to inject the fluid at a programmed rate from the interior of the syringe through the orifice and the tube and into the animal;

then:

unlocking the syringe from the injector and removing the syringe from the opening by forward axial movement thereof with the tube connected to the orifice of the syringe.

20. A method of replacing a tubular replacement syringe in a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:

providing the power injector with a generally circular opening in the front thereof adapted to receive the rearward end of a syringe having a hollow body of generally circular cross-section, the injector having a powered ram operable to move axially along a segment of a line projecting through the opening;

providing a replaceable syringe formed of a cylindrical body having an axis, a hollow interior within the tubular body, a plunger axially slidable in the interior, and closed forward end having a fluid discharge orifice therein;

the body of the syringe being inserted in the opening with the axis thereof parallel to the line, and locked, around a peripheral rim thereof, to the injector around the opening, the plunger being coupled to the ram, and the syringe being structurally capable of withstanding, at least from the peripheral rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

providing linkage relating the angular orientation, about its axis, of the syringe in the opening of the injector and the transverse position of the ram relative to the line; then,

driving the ram forward along the line to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure through the orifice at a programmed rate into an animal;

imparting to the syringe a releasing motion, relative to the injector, to rotate the syringe about the axis and thereby unlock the syringe from the injector and to transversely translate the syringe relative to the ram and thereby uncouple the plunger from the ram; and then,

removing the syringe from the injector by generally forward axial movement of the syringe relative to the opening.

21. The method of claim **20** further comprising the steps of:

inserting a replacement syringe into the opening of the injector by rearward translatory motion; and

simultaneous with the locking of the syringe to the injector, coupling the plunger to the ram by a motion that is the opposite of the imparted releasing motion.

22. A method of replacing a first syringe with a second syringe in a power injector for injecting fluid into an animal, the method comprising the steps of:

providing the injector with an opening at the front thereof and a power driven ram extendable along a line through the opening;

providing a first syringe positioned in the opening, locked to the injector and having a plunger therein coupled to the ram;

completing the injection of fluid into an animal by extending the ram in a programmed manner to force fluid at a pressure of at least 100 psi from the first syringe at a programmed rate;

disconnecting the plunger of the first syringe from the ram while the ram is substantially extended;

unlocking the first syringe from the injector while the ram is substantially extended;

removing the first syringe from the injector by generally forward translatory movement of the first syringe relative to the opening while the ram is substantially extended;

inserting a second syringe into the injector, by generally rearward translatory movement of the second syringe, back end first, into the opening;

locking the second syringe to the injector; and

coupling the ram to a plunger of the second syringe.

23. The method of claim **22** wherein:

the second syringe inserting step is performed while the ram is substantially extended.

24. A method of loading a replacement syringe into a high pressure power injector for injecting fluid into an animal,

wherein the injector has a forwardly extending tubular pressure jacket having an internal space dimensioned to surround and provide pressure restraining support to the body of a syringe positioned in the jacket, a powered ram, and a motor linked to the ram and operable to move the ram at least partially along a line that extends through internal space of the jacket, and

wherein the replacement syringe has a generally tubular body of generally circular cross-section dimensioned to fit in the internal space of the pressure jacket with its external surface in contact with the pressure jacket, the tubular body having a hollow interior, a plunger longitudinally slidable in the tubular body, a rearward end and forward end having a fluid discharge orifice therein,

the method comprising the steps of:

providing the jacket with a generally circular open front end configured to receive the back end of the syringe; and,

providing the syringe with a peripheral rim located near the forward end of the syringe, the syringe being structurally capable of containing, at least from the peripheral rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof; then,

inserting the syringe into the open front end of the jacket, by generally rearward longitudinal movement relative thereto, so that the syringe body, at least from the rearward end to the peripheral rim thereof, is in the internal space of the jacket; then,

rotating the syringe in the jacket to thereby lock the syringe at the peripheral rim thereof to the injector at the front end of the jacket; and,

coupling the plunger to the ram; and then,

energizing the motor and thereby driving the ram forward along the line and into the hollow interior of the syringe to move the plunger forward in a programmed manner to inject fluid at the operating pressure through the orifice at a programmed rate into the animal.

25. The method of claim **24** further comprising the steps of:

providing linkage interconnecting the rotating and coupling steps;

imparting to the syringe a releasing motion to rotate the syringe relative to the jacket and thereby unlock the syringe from the injector and to uncouple the plunger from the ram; and

removing the syringe from the injector by generally forward axial movement of the syringe from the jacket.

26. The method of claim **25** wherein:

the motion imparting step includes the step of translating the plunger transversely relative to the ram to uncouple the plunger from the ram in a motion linked to the rotation of the syringe relative to the jacket.

27. The method of claim 24 wherein:

the locking of the syringe body to the injector includes the step of threading the peripheral rim of the syringe to the jacket around the opening.

28. The method of claim 24 wherein:

the syringe rotating step and the plunger coupling step are performed simultaneously.

29. The method of claim 24 wherein:

the coupling of the plunger to the ram occurs upon the performance of the syringe rotating step.

30. The method of claim 24 further comprising the step of:

after coupling the plunger to the ram and before the step of energizing the motor and thereby driving the ram forward, retracting the ram and thereby rearwardly moving the plunger and thereby drawing fluid into the second syringe.

31. A method of loading an empty syringe into a power injector for injecting fluid into an animal and for filling the syringe with the fluid to be so injected, the syringe having a tubular body with a hollow interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger moveable in the hollow interior between the rearward end and forward end, and wherein the injector has a syringe mount and a power driven ram extendable therefrom, the method comprising the steps of:

securing an empty syringe to the syringe mount of the injector with the plunger in an initial position proximate the forward end of the syringe body;

providing the ram in a forward position extending from the injector, through the rearward end of the body of the syringe and into the hollow interior thereof;

coupling the ram, while in the forward position in the hollow interior of the syringe body, to the plunger while the plunger is in its initial position proximate the forward end of the tubular syringe body;

connecting a supply of fluid to the discharge orifice; and,

energizing a ram drive to translate the coupled ram rearwardly from the forward position to thereby move the plunger rearwardly in the body to draw fluid into the interior of the syringe through the orifice from the connected supply.

32. The method of claim 31 wherein:

the syringe mount of the injector has syringe-receiving structure supported by the injector, the power driven ram being extendable through the syringe-receiving structure;

the method further comprises the step of translating the rearward end of the syringe toward and into the syringe-receiving structure; and,

the securing step includes the step of locking the syringe to the syringe-receiving structure while the rearward end of the syringe is in the syringe receiving structure.

33. The method of claim 31 further comprising the steps of:

after drawing fluid into the interior of the syringe body, disconnecting the supply from the orifice;

thereafter, connecting a tube between the orifice and the animal; and,

then energizing the ram drive to translate the ram forwardly in a programmed motion to thereby translate the plunger of the syringe forwardly to inject a programmed flow of fluid from the hollow interior of the body of the syringe, through the orifice and the tube connected thereto, into the animal.

34. The method of claim 31 wherein:

the syringe mount of the injector has syringe-receiving structure supported by the injector, the power driven ram being extendable through the syringe-receiving structure;

the method further comprises the step of translating the rearward end of the syringe longitudinally rearwardly, toward the syringe-receiving structure, while the ram is in the forward position and before securing the syringe to the syringe mount of the injector; and

the securing step includes the step of locking the syringe to the syringe-receiving structure.

35. The method of claim 31 further comprising the step of:

loading the syringe onto the injector while the ram is in the forward position and before securing the syringe to the syringe mount of the injector.

36. A method of loading an empty syringe into a power injector for injecting fluid into an animal and for filling the syringe with the fluid to be so injected, the syringe having a tubular body with a hollow interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger moveable in the hollow interior between the rearward end and forward end, and wherein the injector has a syringe mount and a power driven ram extendable therefrom, the method comprising the steps of:

providing the ram in a forward position extending from the injector, through the rearward end of the body of the syringe and into the hollow interior thereof;

securing an empty syringe to the syringe mount of the injector with the ram in its forward position;

coupling the ram to the plunger while the ram is in its forward position;

connecting a supply of fluid to the discharge orifice;

energizing a ram drive to translate the coupled ram rearwardly from the forward position to thereby move the plunger rearwardly in the body to draw fluid into the interior of the syringe through the orifice from the connected supply.

37. The method of claim 36 wherein:

the coupling step includes the step of coupling the ram to the plunger within the hollow interior of the tube while the plunger is remote from the open rearward end of the tubular body.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,456,669
DATED : October 10, 1995
INVENTOR(S) : Charles Neer, et al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

In the claims:

In claim 19, column 16, line 60, "the and" should be deleted and --the orifice and-- should be inserted.

In claim 20, column 17, line 28, "line" should read as --axis--.

Signed and Sealed this
Twentieth Day of August, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

US005658261A

United States Patent [19]

Neer et al.

[11] Patent Number: 5,658,261

[45] Date of Patent: *Aug. 19, 1997

[54] **DISPOSABLE FRONT LOADABLE SYRINGE**

[75] Inventors: **Charles Neer**, Milford; **Frank M. Fago**, Mason, both of Ohio; **Paul E. Dieterlen**, Covington, Ky.; **James H. Goethel**, Cincinnati, Ohio

[73] Assignee: **Liebel-Flarsheim Company**, Cincinnati, Ohio

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,279,569.

[21] Appl. No.: **417,823**

[22] Filed: **Apr. 6, 1995**

Related U.S. Application Data

[62] Division of Ser. No. 195,382, Feb. 14, 1994, Pat. No. 5,451,211, which is a continuation of Ser. No. 712,110, Jun. 7, 1991, Pat. No. 5,300,031.

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/240**; 604/154; 604/218; 128/DIG. 1; 128/655

[58] **Field of Search** 604/154, 232, 604/155, 241, 242, 131, 151, 152, 187, 218, 228, 240; 128/DIG. 1, 654, 655; 222/326, 327, 390

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,542,024	11/1970	Benice .	
3,880,138	4/1975	Wootten et al. .	
4,006,736	2/1977	Kranys et al. .	
4,123,091	10/1978	Cosentino et al. .	
4,254,773	3/1981	Waldbillig .	
4,323,065	4/1982	Kling .	
4,345,595	8/1982	Whitney et al. .	
4,464,265	8/1984	Joyner .	
4,465,473	8/1984	Ruegg .	
4,573,978	3/1986	Reilly	604/240
4,582,218	4/1986	Ross .	
4,677,980	7/1987	Reilly et al. .	
4,695,271	9/1987	Goethel .	
4,744,786	5/1988	Hooven .	
4,936,833	6/1990	Sams	604/232
4,966,601	10/1990	Draenert	604/232
5,007,904	4/1991	Densmore .	
5,085,643	2/1992	Larkin et al. .	
5,279,569	1/1994	Neer et al.	604/154
5,300,031	4/1994	Neer et al.	604/154
5,383,858	1/1995	Reilly et al. .	
5,451,211	9/1995	Neer et al.	604/154

FOREIGN PATENT DOCUMENTS

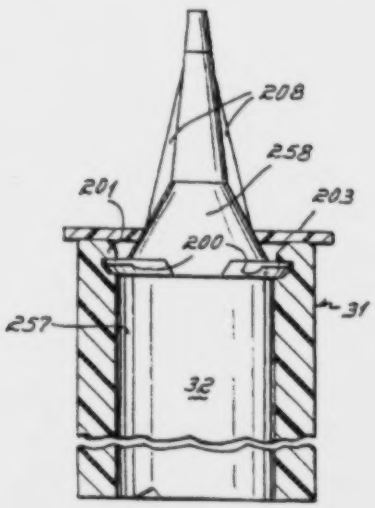
WO90/01962	3/1990	WIPO .

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Attorney, Agent, or Firm—Wood, Herron & Evans, L.L.P.

[57] **ABSTRACT**

An animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is loadable and unloadable into and from the injector through the open front end of a pressure jacket of the injector, thereby permitting replacement without retraction of the syringe plunger drive or disconnection of the injection tubing. The syringe is provided with a pressure restraining front end, such as an integral or removable cap with structure such as threads that lock the syringe to the front end of the jacket by mating with threads on the jacket. A mechanism in the injector, which includes, for example, a key on cam ring operated by a lever with one hand of an operator, interacts with structure such as symmetrically spaced notches on the back end of the syringe to, for example, rotate the syringe and simultaneously translate or rotate a coupling on the syringe plunger into and out of engagement with the plunger drive in the injector.

37 Claims, 11 Drawing Sheets



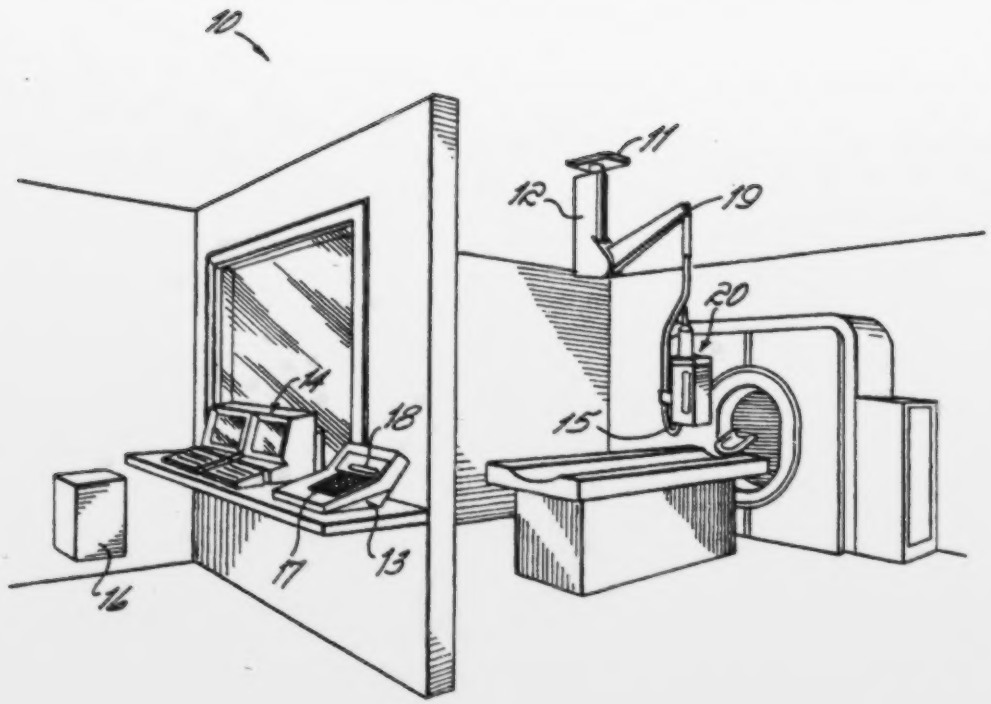


FIG. 1

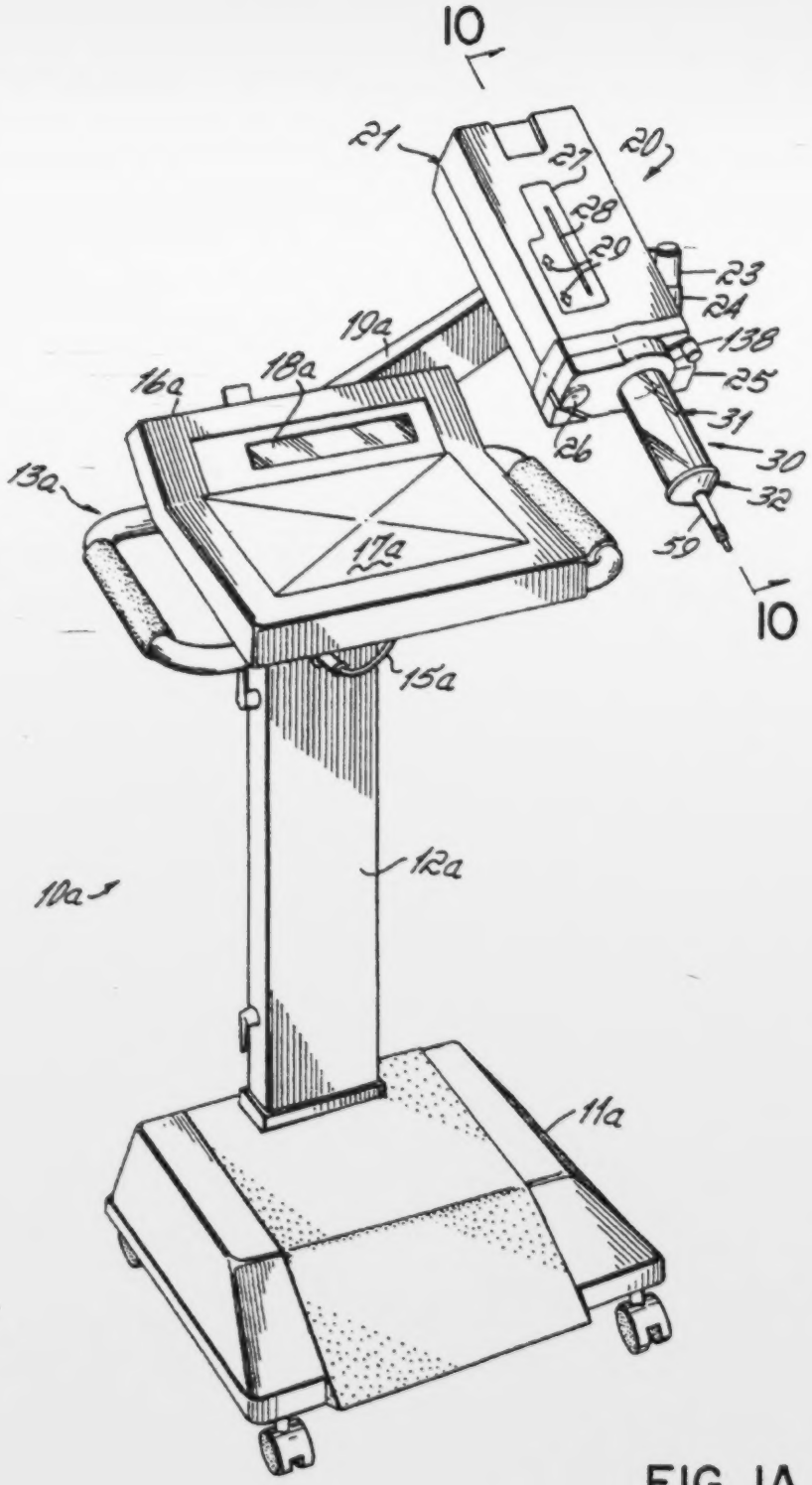

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FIG. 1A

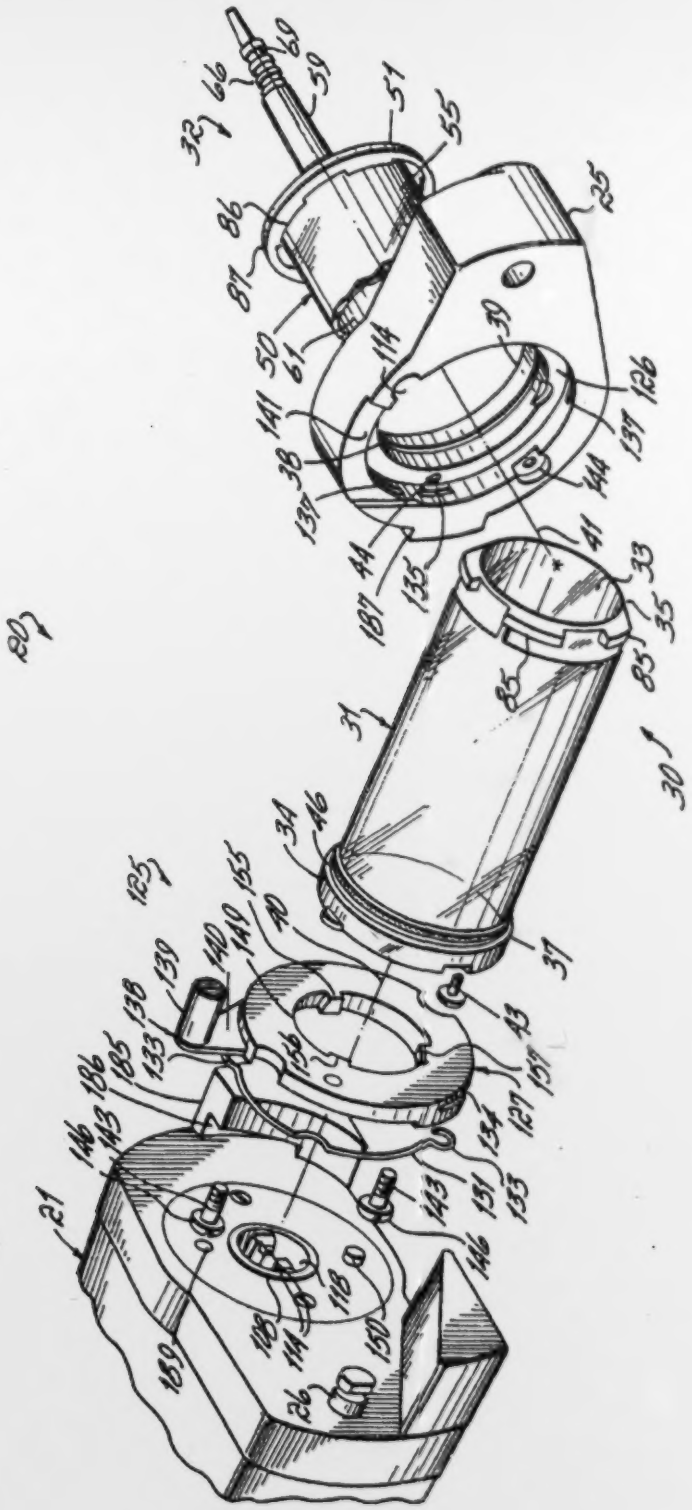

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FIG. 2

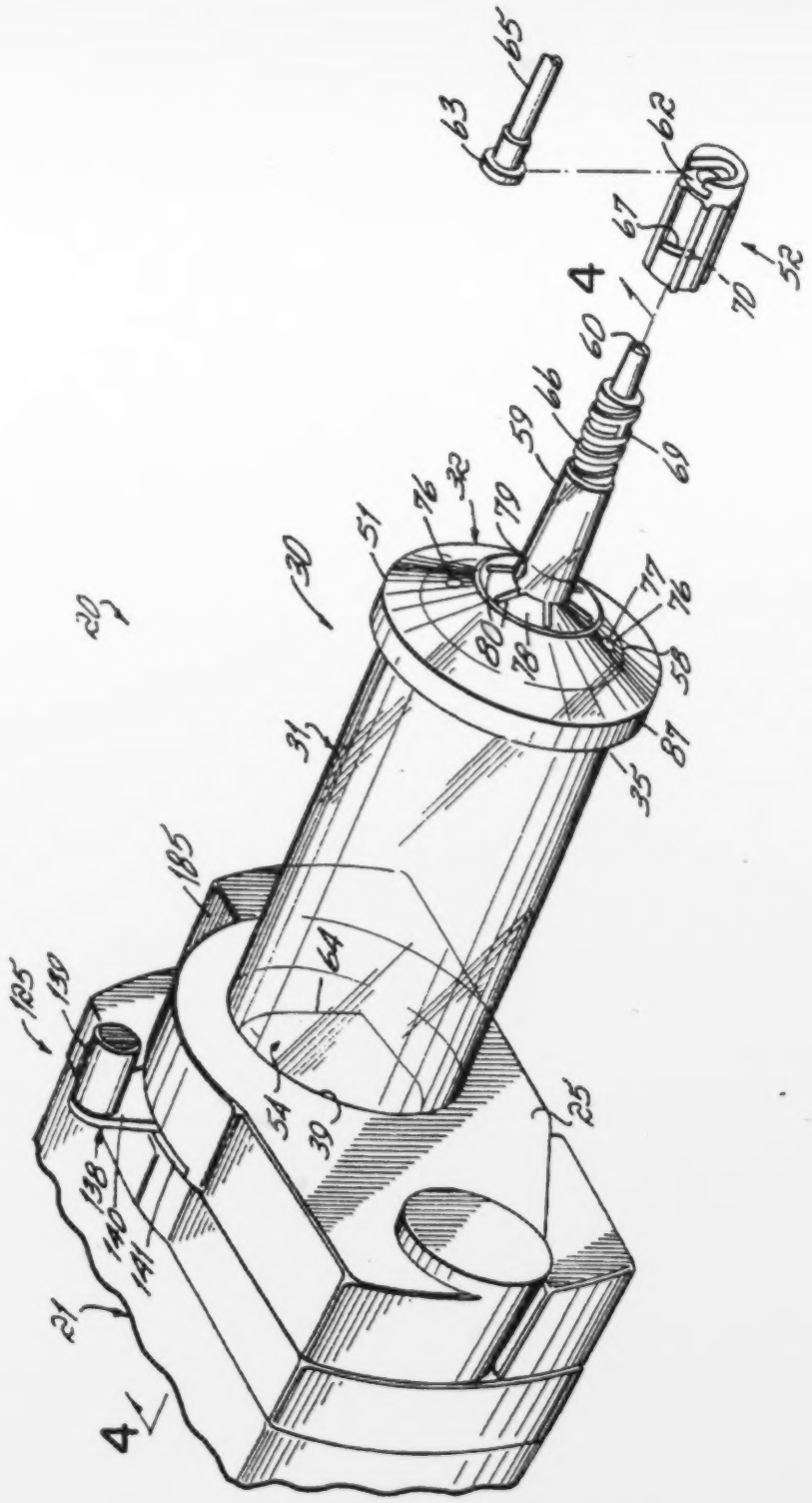

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FIG. 3

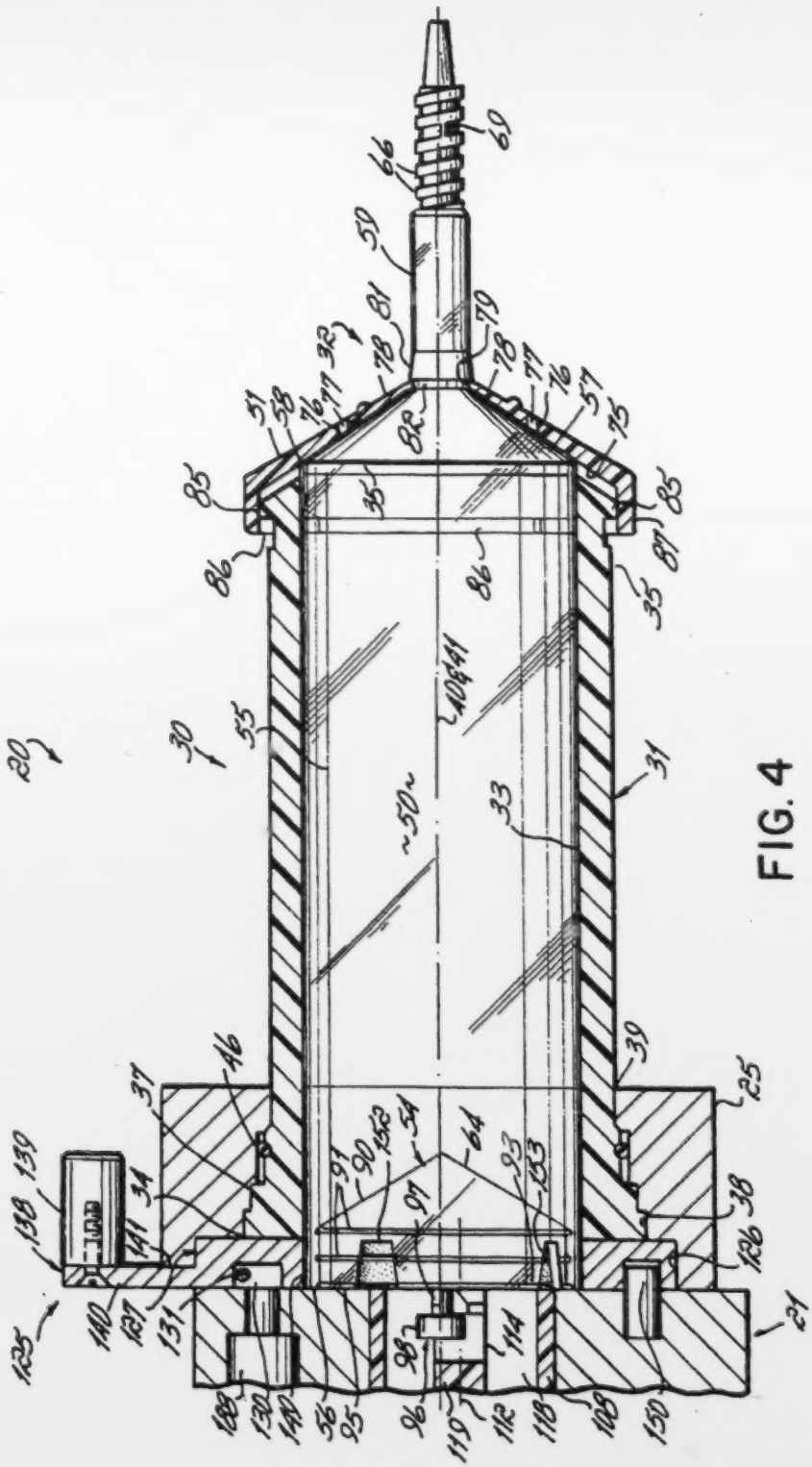


FIG. 4

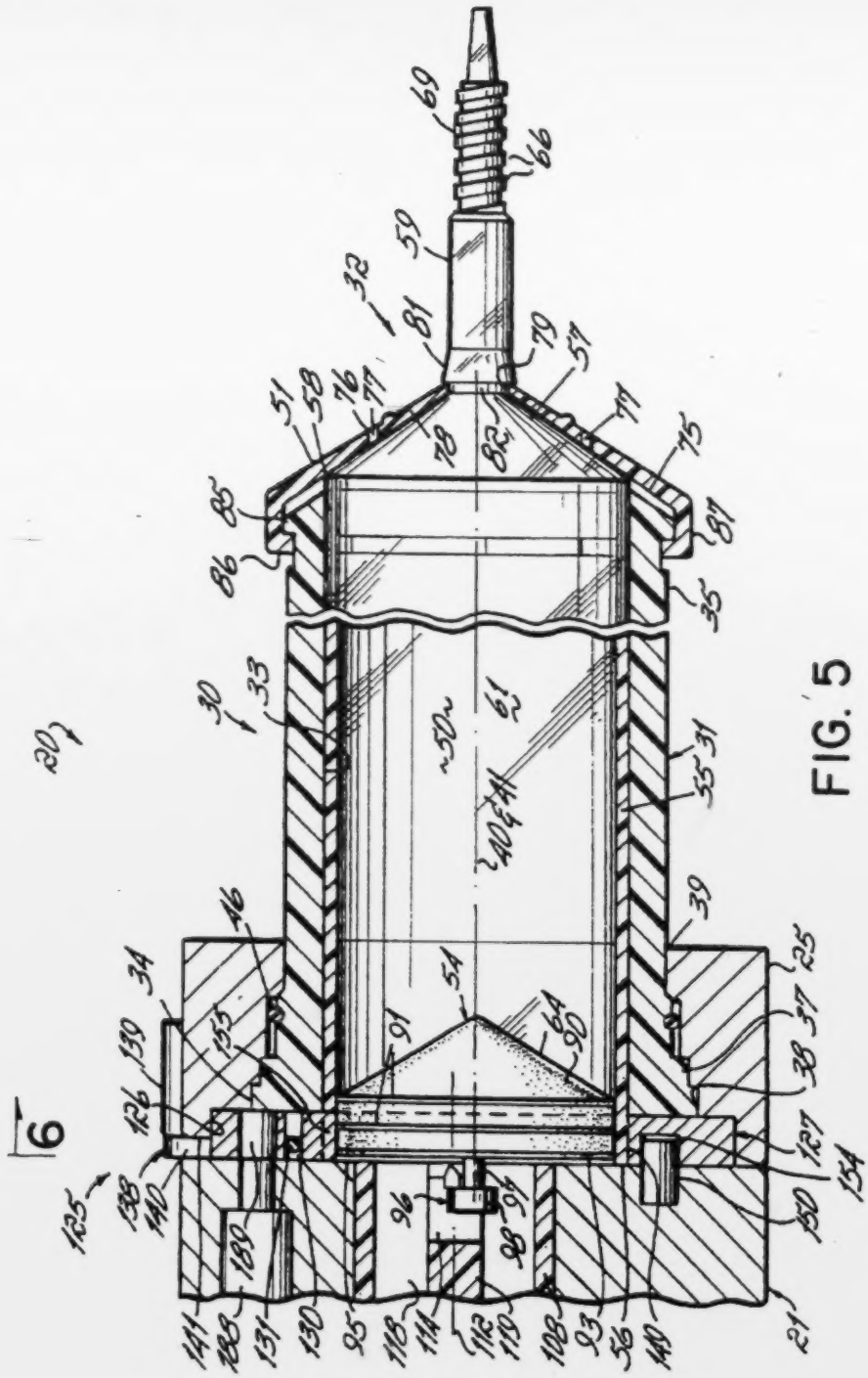

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FIG. 5

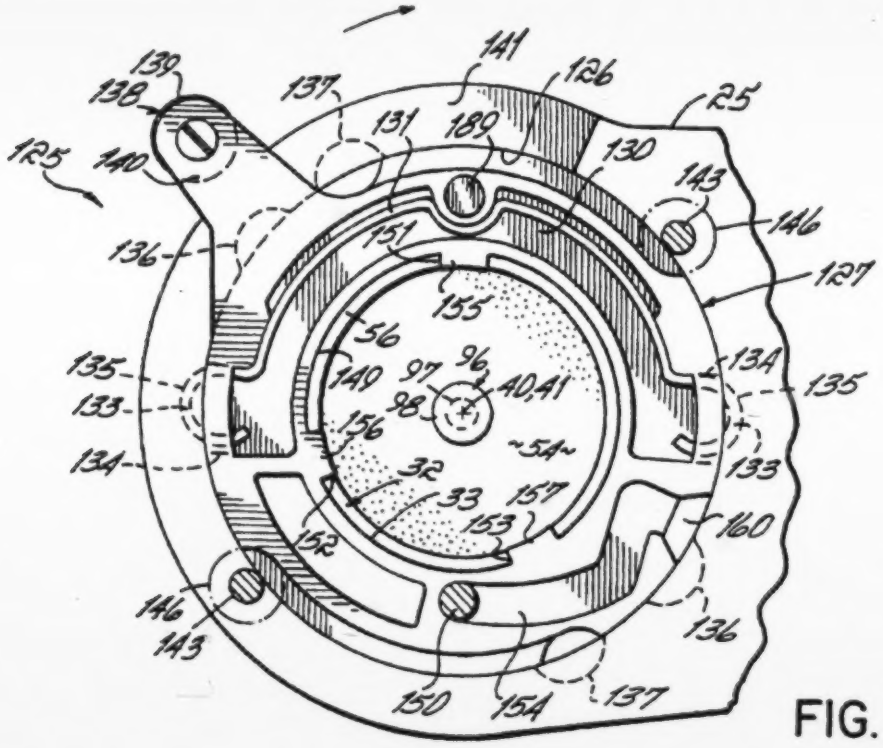


FIG. 6

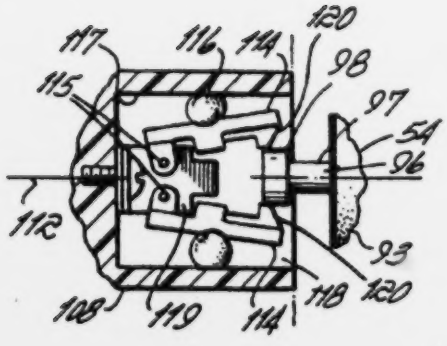


FIG. 11

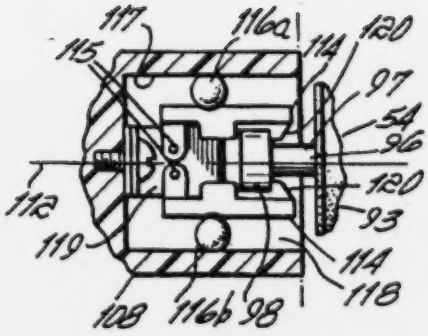


FIG. 12

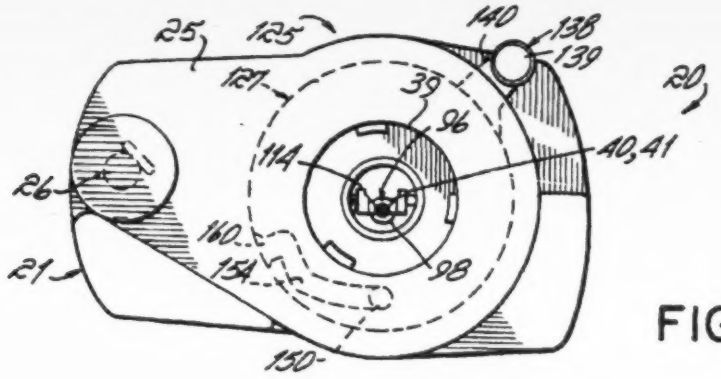


FIG. 7

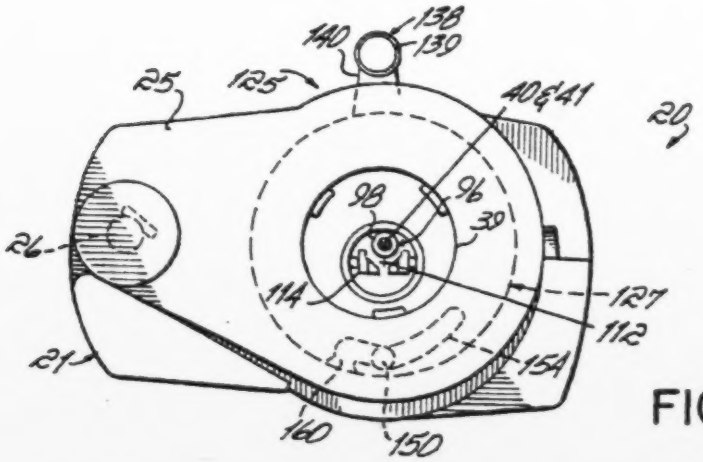


FIG. 8

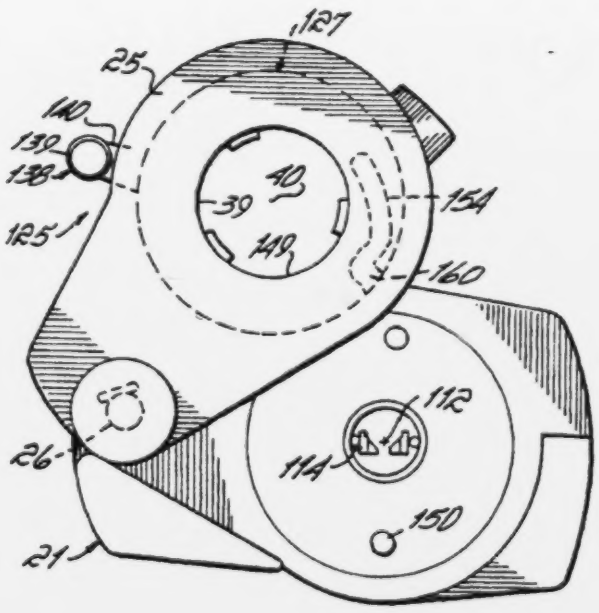


FIG. 9

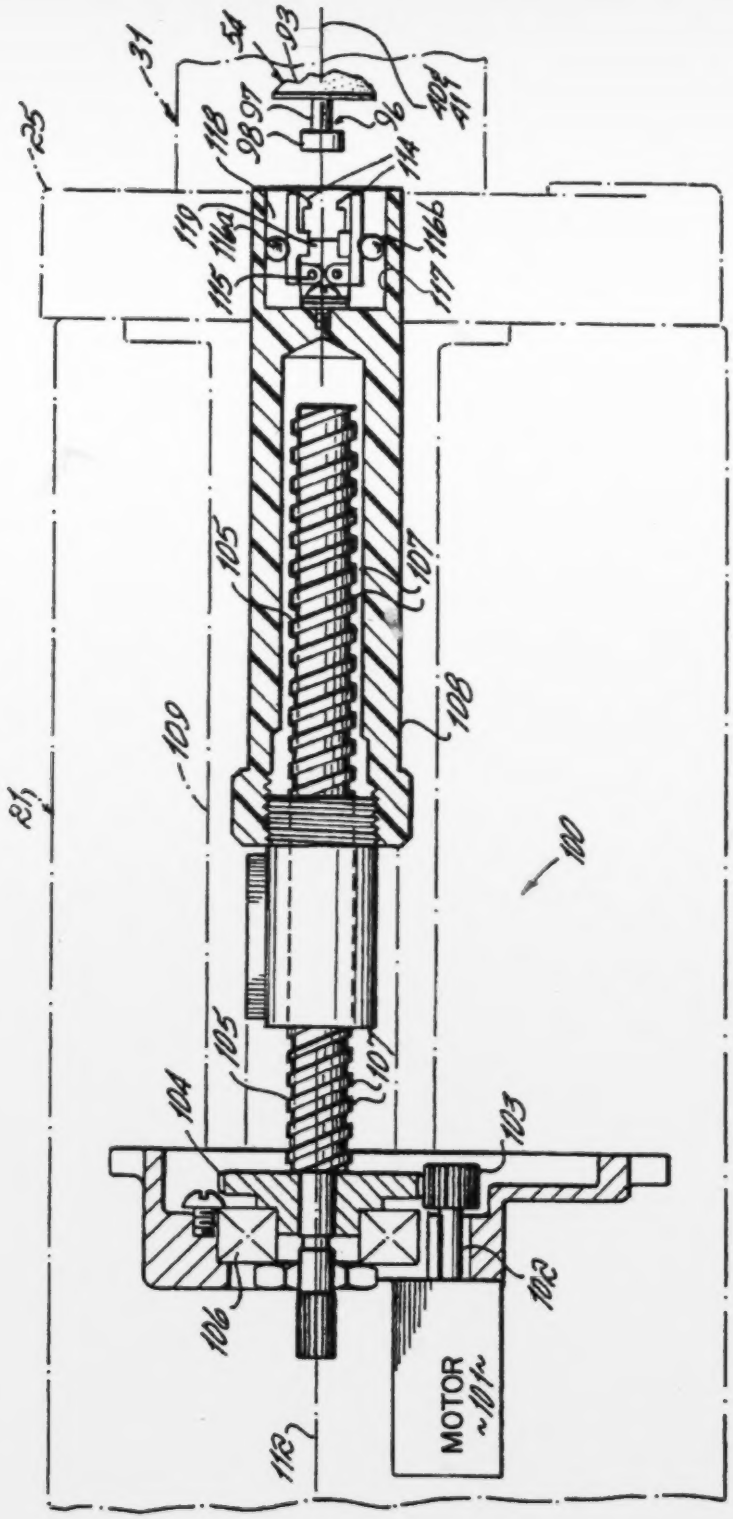


FIG. 10

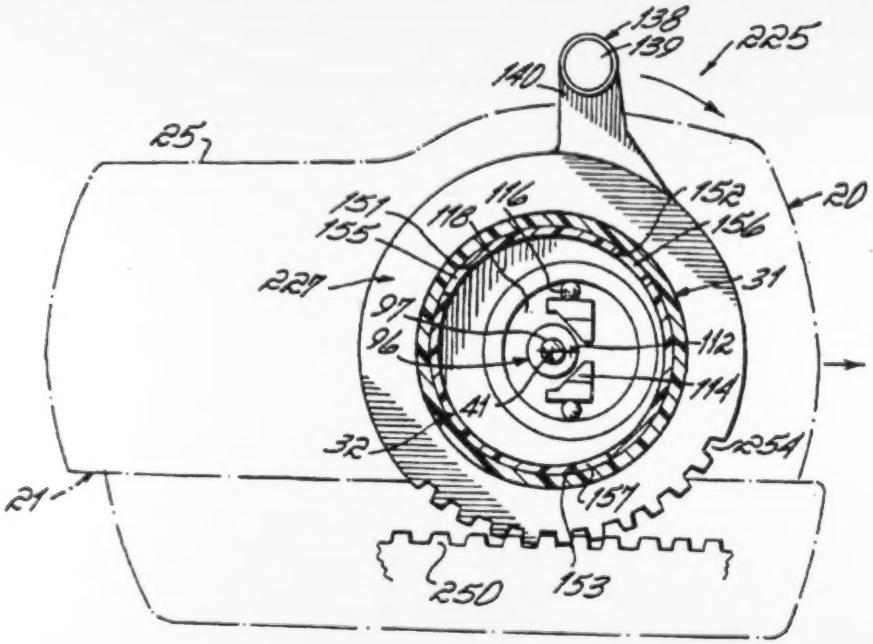

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FIG. 13

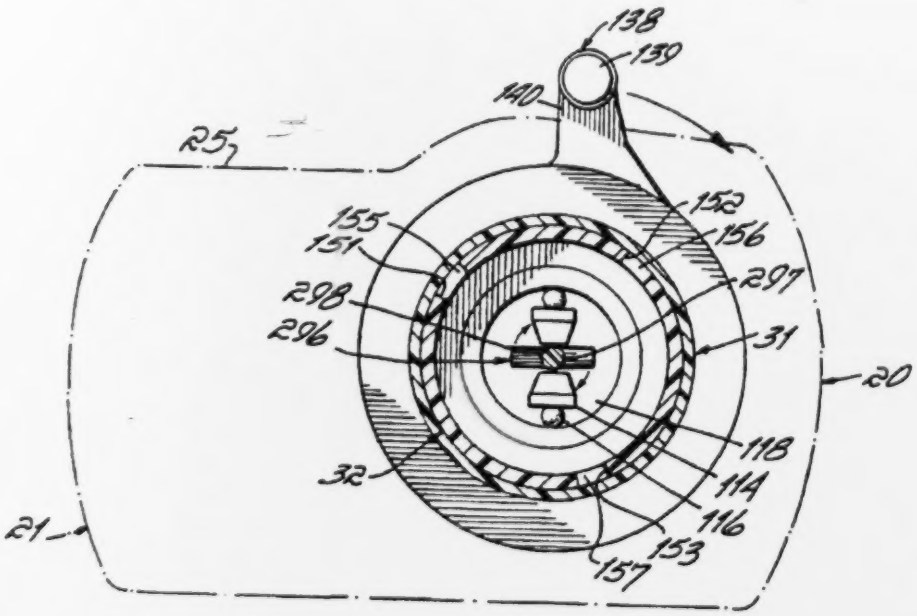

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FIG. 14

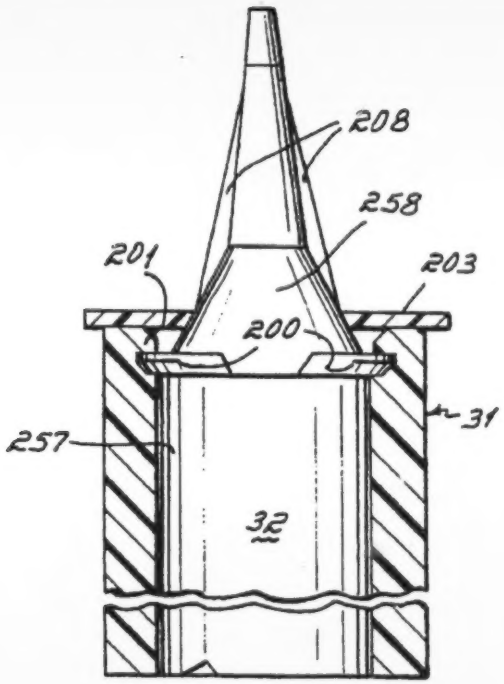


FIG. 15

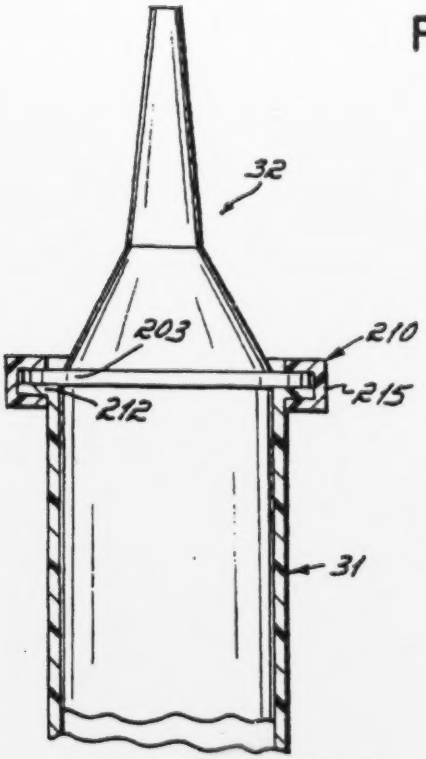


FIG. 16

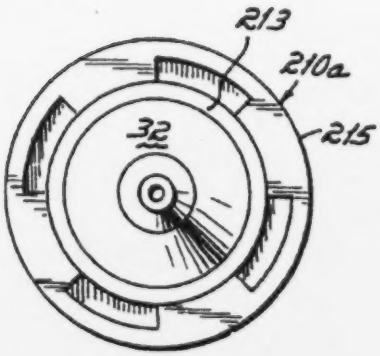


FIG. 17

DISPOSABLE FRONT LOADABLE SYRINGE

This is a divisional of application Ser. No. 08/195,382, filed Feb. 14, 1994, now U.S. Pat. No. 5,451,211 of application Ser. No. 07/712,110, filed Jun. 7, 1991, now U.S. Pat. No. 5,300,031.

FIELD OF THE INVENTION

The present invention relates to injectors and more particularly to disposable replacement syringes for animal fluid injectors.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as contrasting media, from a syringe and through a tube into an animal. The injectors are provided with an injector unit, usually adjustably fixed to a stand or support, having a drive that couples to the plunger of the syringe to drive it forward to expel fluid into the tube, or that may be driven rearward to draw fluid into the syringe to fill it. Usually the syringe is a disposable replacement type.

In the injection phase where the plunger is driven forward, pressures are developed in the syringe that range from, for example, twenty-five psi for some applications to over 1000 to 1200 psi for other applications. Syringes that will contain fluid under such pressures are expensive and therefore impractical where the syringes are to be disposable. Accordingly, many such injectors, such as angiographic injectors, for example, have been provided with pressure jackets fixed to the injector units and into which the syringes are inserted. The pressure jackets contact the outer surfaces of the syringe to restrain the walls of the syringe against the internal pressures.

To hold the syringes in the pressure jackets, the jackets of the prior art have been configured to surround the front ends of the syringes to restrain the syringe front wall against forward acting forces of the drive and the fluid pressure and to hold the syringe in the jacket. Because the front end of the pressure jacket is closed, rear loading was necessary, and accessibility thereto was provided by hinging or rotating the jacket to allow for removal and replacement of the syringe from the rear. The opening and reclosing of the injector unit to replace the syringe requires a certain amount of time, which, in the course of the procedure being performed, is not wholly desirable.

Furthermore, while for many years injector units of various types have been capable of disconnection of the plunger drive from the drive coupling on the syringe plunger at any position of the plunger within the syringe, retraction of the drive is typically required before the syringe can be removed. This is because the opening of the injector unit to remove and insert the syringe from the rear requires, for example, a translating or rotating of the jacket from the axis of the drive, which cannot be achieved if the plunger drive is extended.

For example, at the end of an injection procedure, the syringe plunger typically is forward, as is the plunger drive. Since, in the prior art injectors that load from the rear, the pressure jacket is moved through the position that the drive occupies when extended in order to remove the syringe. Hence, the syringe cannot be immediately removed without retracting the plunger drive. Further, the disposable tubing that connects to the nozzle of the syringe must be disconnected from the syringe in order to remove the syringe from the jacket. Additionally, when an empty new syringe is inserted, the drive must be in its retracted position.

More often than not, the syringe is inserted empty and filled by retraction of the plunger with an injection tube connected to a supply of the fluid that is to be injected. In addition, before an empty new syringe can be filled it is necessary that the plunger be fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. As a consequence of the need with such prior art injectors to retract the drive upon loading the syringe, it is then necessary to fully advance the drive to the position in which it is in engagement with the plunger and the plunger is in its full forward position. The drive then engages a coupling on the plunger of the replacement syringe. This need to retract and advance the drive contributes to a loss of time in the syringe replacement process.

Accordingly, there has been a need to more quickly load and unload disposable replacement syringes in angiographic injectors, and for injectors and replacement syringes that can accommodate a more efficient process of syringe replacement.

SUMMARY OF THE INVENTION

It is an objective of the present invention to provide a method and apparatus by which replaceable syringes can be more efficiently loaded into and unloaded from injectors.

It is a more particular objective of the present invention to provide an injector, more particularly an angiographic injector, a replacement syringe therefor, and a method of replacing the syringe in the injector that provide for more efficient replacement of the syringes in the injector. It is an additional objective of the present invention to provide an injector wherein a used syringe can be removed and a new one inserted in the injector without retraction of the drive from the pressure jacket, in most applications. It is a further objective of the invention to allow for the removal of the used syringe from the jacket without disconnection of the injector tube from the syringe nozzle.

It is still a further objective of the present invention to provide an injector, replaceable syringe and method of syringe replacement with which the replacement of the syringe can be achieved with simple motions by the operator or with rapid operation of injector unit mechanisms.

An additional objective of the present invention is to provide an injector and replaceable syringe therefor that will facilitate control of the orientation of the syringe in the jacket, and thereby provide for positive, rapid and reliable engagement of the syringe with locking structure that holds the syringe in the jacket, engagement of the plunger drive and plunger drive coupling, or connection of the injection tube to the outlet of the syringe.

A further objective of the present invention is to provide for easy to operate mechanism and reliable locking structure for locking the syringe in place in the pressure jacket of the injection unit.

Another objective of the present invention is to provide an injector and syringe arrangement that minimizes or eliminates the probability of spillage from the syringe nozzle flowing into the injector equipment, and otherwise enhancing the ability to maintain sterility and cleanliness of the equipment.

According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is provided in the front end of the pressure jacket. To provide this front end loadable feature, the syringes of the preferred and illustrated embodiments of the present invention are

provided with a front wall that is pressure restraining, that is, is of sufficient strength to support the front of the syringe against the expected pressures within the syringe, and that is securable to the front end of the pressure jacket so as to complete the pressure restraining enclosure of the syringe within the pressure jacket and hold the syringe in the jacket. In one preferred form, this front end of the injector is formed of a separate pressure restraining cap made of material that is separate from the front wall of the syringe and may be reusable. In another preferred form, the cap may be formed integrally of the front syringe wall. With the cooperating structure of the jacket and the syringe, restraining of the pressure jacket along the front and sides of the syringe is provided where the jacket allows for the replacement of the syringe from the front.

In one preferred and illustrated embodiment of the invention, the front end of the syringe locks to the front end of the pressure jacket through a cooperating engagement of mating threads on the syringe jacket. The threads include external thread sections formed at the front end of the pressure jacket and internal threads formed on an outwardly extending flange or rim of the front wall of the syringe, preferable on a pressure restraining cap. Alternatively, other securing or locking structure such as a clip or an adaptor, for example, may be employed to join the syringe to the jacket.

In the preferred embodiment of the present invention, the threads are engageable in a limited number of angular positions to thereby predetermine the angular orientation of the syringe in the pressure jacket. Additionally, other keys and keyways carried respectively by the unit and by the syringe limit the angular position in which the syringe may be inserted into the jacket to a unique predetermined angular orientation. Preferably, three keyways, such as slots or notches, unequally spaced around the back, rearward or proximate edge of the syringe body, engage similarly spaced keys or tabs on the unit at the rear end of the pressure jacket to permit insertion of the syringe into the jacket in one and only one orientation.

Further in accordance with principles of the present invention, in its preferred embodiment, a coupling on the syringe plunger is centrally located and symmetrical about the axis of the plunger. A pair of jaws on the plunger drive is moveable either by transverse straight or arcuate translatory motion or by forward longitudinal motion to form a connection between the coupling and the drive. Once coupled to the drive, the coupling remains engaged to the drive during longitudinal motion of the drive to cause the plunger to move forward or backward with the drive. Disengagement occurs thereafter only upon transverse translational motion of the plunger with respect to the drive. In certain embodiments, this translatory transverse motion occurs by translatory movement of the jacket, and the injector unit door that carries the jacket, with respect to the plunger drive and the unit housing. In other embodiments, an asymmetrical coupling is provided that engages and disengages the plunger drive upon rotational movement of the syringe with respect to the drive.

Preferably, the motion for locking the syringe to, and unlocking the syringe from, the jacket is achieved by rotation of the syringe in the jacket, and preferably, this motion is linked to, and occurs simultaneous with, the motion that engages and disengages the plunger coupling and drive, whether that coupling is by translation or rotation. In addition, the syringe and plunger drive are so dimensioned and positioned to prevent contact between the drive and the sterile interior wall of the syringe, regardless of the position of the drive, as the syringe is being loaded.

Preferably, the syringe is formed of a cylindrical body, with the front end in the shape of a truncated cone that terminates in a forwardly extending neck with an orifice at its remote end that is connectable with an injection tube. The front end of the syringe is shaped so as to direct fluid leaking from the nozzle outwardly around the front end of the jacket. This prevents leakage, which often results upon disconnection of the injection tubing, from entering the space between the pressure jacket and the syringe body.

Replacement of the syringe begins, in the preferred embodiments of the invention, with unlocking the syringe at its front end from the front end of the pressure jacket, preferably by rotating the syringe with respect to the jacket, and by disengaging the plunger drive from the syringe plunger, alternatively by transverse translational or rotational motion, preferably simultaneous with and linked to the motion that disengages the syringe from the jacket. The unlocking of the syringe from the jacket occurs, for example, by loosening mating threads at the front of the syringe and jacket. The twisting of the syringe in the jacket is linked to motion that either translates transversely or rotates a coupling on the syringe plunger out of engagement with the plunger drive.

Then the syringe is removed from the jacket through the open front end of the jacket. This removal may take place without retraction of the plunger drive, should the drive be advanced in the pressure jacket at the time of disengagement from the plunger coupling. The used syringe may also be removed without disconnection of the disposable injection tubing from the nozzle of the syringe.

When the used syringe is removed, a replacement syringe is inserted into the jacket through its open forward end and the front end of the new syringe is locked to the front end of the jacket, preferably by relative rotation of the syringe in the jacket to cause, for example, engagement between mating threads on the front end of the syringe and the front end of the jacket. The plunger drive, in one embodiment, is translated to bring the plunger coupling engaging jaws into alignment with the plunger coupling, preferably simultaneously with the locking of the syringe to the jacket. The jaws thereby either engage the coupling upon the translatory motion, or thereafter engage the coupling by longitudinal advancement of the drive against the coupling. In one embodiment, the jaws are positioned off center of the drive so that the drive, whether in the engaging or the disengaging positions, does not contact a syringe as the syringe is guided by the jacket during loading.

In an alternative embodiment, engagement of the plunger drive with the coupling occurs by relative rotation of the drive and the coupling, preferably by rotating the coupling relative to a stationary plunger drive, rather than by translational motion between the drive and the coupling. Only if the rest position of the plunger of the replacement syringe is behind the final position of the plunger drive at the time it was disconnected from the coupling of the plunger of the syringe being replaced need the plunger drive be retracted.

The engagement and disengagement motions between the plunger drive and plunger drive coupling, and between the syringe and the pressure jacket, are provided with manually operable mechanism that, in the preferred and illustrated embodiments, rotates the syringe in the jacket and further either rotates or translates the coupling with respect to the plunger drive, with a simple one hand operated mechanism. The mechanism provides a convenient lever, operable through a short arc, to rotate the syringe in the jacket and to then, preferably, translate the pressure jacket that carries the

syringe and is carried by the injector unit door, or to otherwise move the syringe with respect to the drive, to bring the plunger coupling of the syringe into or out of alignment with the plunger drive.

The present invention provides a disposable syringe that may be replaced in an angiographic or CT injector with great efficiency and speed. Further, replacement may occur without retraction of the plunger drive of the injector unit. Simple and rapid one hand operation of the engaging and disengaging structure is provided.

These and other objectives of the present invention will be more readily apparent from the following detailed description of the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an angiographic CT injector embodying principles of the present invention.

FIG. 1A is a perspective view of an another form of angiographic injector embodying principles of the present invention.

FIG. 2 is an exploded perspective view of a portion of one preferred embodiment of the injector of FIG. 1.

FIG. 3 is a perspective view of the portion of the injector of FIG. 2.

FIG. 4 is a cross-sectional view along lines 4—4 of FIG. 3 illustrating a replaceable syringe unlocked from the housing for insertion into or removal therefrom.

FIG. 5 is a cross-sectional view similar to FIG. 4 but illustrating the syringe locked to the structure carried by the housing.

FIG. 6 is a cross-sectional view along the line 6—6 of FIG. 5.

FIG. 7 is an elevational diagrammatic illustration of the injector of FIG. 1 with the pressure jacket and syringe removed, and showing the syringe locking structure in the locked position such as in FIGS. 5 and 6.

FIG. 8 is an elevational diagrammatic view similar to FIG. 7 illustrating the syringe locking structure in the unlocked position such as in FIGS. 2–4.

FIG. 9 is an elevational diagrammatic view similar to FIG. 7 illustrating the locking mechanism in the housing door release position.

FIG. 10 is a cross-sectional view through the housing of the injector taken along lines 10—10 of FIG. 1A with the plunger drive disengaged from the syringe plunger coupling.

FIG. 11 is a view of a portion of FIG. 10 illustrating the plunger drive longitudinally moving into engagement with the plunger coupling.

FIG. 12 is a view of a portion of FIG. 10 illustrating the plunger drive in engagement with the plunger coupling.

FIG. 13 is a front view of a portion of another embodiment of the injector of FIG. 1.

FIG. 14 is a view of an alternative embodiment of a portion of a syringe according to principles of the present invention.

FIG. 15 is a cross-sectional view similar to FIG. 5 of an alternative embodiment of the invention, illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. 16 is a cross-sectional view similar to FIG. 5 of a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. 17 is a front end view of still a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. 1, an angiographic injector 10 according to another preferred embodiment of the present invention is illustrated, configured for CT applications. The injector 10 includes a ceiling mounted support 11, adjacent a CT X-ray unit, to the lower surface of which is rigidly supported a vertically descending support column 12.

Remote from the support 11 is an injector control module console 13 behind a wall which isolates the operator area from the X-ray equipment. The console 13 is located adjacent a control 14 of the X-ray equipment. Electrical power and control cables (not shown) communicate power and control signals through the support 11 and the column 12 and to a power lead 15. The console 13 connects with an injector control module 16, which includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard 17 on the console 13. The console 13 is also provided with an operator display 18 to aid in interfacing the input commands and injector status with the operator.

Attached to the column 12 is an articulating adjustable arm 19. To the remote end of the arm 19 is adjustably supported injection module unit 20. The arm 19 is capable of setting the unit 20 at varying positions adjacent a patient bed of the CT unit.

Referring to FIG. 1A, an angiographic injector 10a according to another preferred embodiment of the present invention is illustrated. The injector 10a includes a wheeled base 11a to the top of which is rigidly supported a vertically adjustable upstanding support column 12a. To the top of the column 12a is supported a control module platform 13a. Electrical power is communicated from a power cord (not shown) through the base 11a and the upstanding support 12a and through a power lead 15a to a control module 16a rigidly supported to the platform 13a. The control module 16a includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard 17a on the module 16a. The module 16a is also provided with an operator display 18a to aid in interfacing the input commands and injector status with the operator. Attached to the platform 13a is an articulating adjustable arm 19a. To the remote end of the arm 19a is adjustably supported the injection module unit 20.

The injection module unit 20 of the embodiments of FIGS. 1 and 1A includes a housing 21 which contains the operating drive structure of the injector 10 or 10a. The housing 21 has a support bracket 23 fixed thereto and adjustably pivotally supported to the remote end 24 of the articulating arm 19 or 19a. The housing 21 has pivotally attached to the front thereof a door 25 at the front thereof which is pivotally connected to the housing 21 at a longitudinally extending pivot or hinge pin 26 (FIG. 2) rigidly supported on the housing 21 and extending forwardly from the front of the housing 21.

On the top of the housing 21 is an injector position and local control panel 27 having a position indicator scale 28 thereon, which displays the position of the injector drive to the operator. The panel 27 also includes a pair of forward and reverse drive direction control buttons 29, which are selectively actuatable to activate a drive within the housing 21 in either the forward or reverse directions.

Extending forwardly from the front of the door 25 is an injector syringe and pressure jacket assembly 30, the structure of which can be better understood with reference to FIGS. 2–5 below. The syringe and jacket assembly 30 includes a hard plastic pressure jacket 31, which may be of opaque or transparent material, a removable and replaceable disposable syringe 32, which may be of opaque, transparent or semi-transparent material, and related structure hereinafter described.

The syringe 32 is disposable, and includes walls which will withstand only moderate or low pressure. The walls are usually outwardly deformable under operating pressures, particularly pressures of 300 psi or more. Such higher pressures are necessary to overcome pressure drops through the injection tubing at higher flow rates, which are often desirable. The jacket 31 is made of a stronger transparent material that will withstand the operating pressures. When the syringe 32 is contained in the jacket 31, it is surrounded by the jacket 31 and supported by the jacket 31 against expansion caused by the fluid pressure within as the syringe 32 expands against the jacket wall.

The pressure jacket 31 has a generally cylindrical inner bore 33 extending therethrough from a proximate end 34 adjacent the door 25 to a remote end 35 of the pressure jacket 31 toward the front of the unit 20. The bore 33 is dimensioned so as to receive through the remote end 35 the disposable syringe 32 and to support the syringe against expansion from fluid pressure within such fluid pressure may range to more than a thousand psi. The pressure jacket 31 has an annular flange 37 extending outwardly around the proximate end 34. The flange 37 is integrally formed with the jacket cylinder and is shaped to conform to an annular recess 38 surrounding a circular hole 39 in the door 25 to which the jacket 31 may be assembled by insertion from the rear. The hole or opening 39 in the door 25 and the cylindrical bore 33 of the jacket 31 are concentric with a longitudinal axis 40 on which also lies an axis 41 of the syringe 32 when the syringe 32 is positioned in the bore 33 of the jacket 31. The jacket 31 is firmly and rigidly attached to the door 25 with a pair of screws 43, only one of which is shown, which are threaded into a pair of holes 44 in the back of the door 25 (FIG. 2). An O-ring seal 46 surrounds the flange 37 of the jacket 31 in the recess 38 of the door 25.

The syringe 32 includes a syringe case 50 formed of a single piece of molded plastic material, a pressure cap 51, a tubing collar 52 (FIG. 3) and a plunger 54 (FIGS. 3–5). The syringe case 50 includes a cylindrical syringe body 55 having an open proximate end 56 and a remote end 58 to which is integrally formed a conical front wall 57. The front wall 57 is truncated at its forward end, to which is integrally formed an elongated neck 59 extending from the wall 57 at the center thereof. The neck 59 of the syringe case 50 has an orifice 60 (FIG. 3) in its remote end which communicates with an internal syringe cavity 61 formed within the neck 59, the conical front wall 57 and the cylindrical body 55 of the case 50 of the syringe 32. The rear end of the cavity 61 is further defined by a forward facing conical surface 64 of the plunger 54. The conical surface 64 is of a slope which conforms to the slope of the interior of the conical front wall 57. The plunger 54 is slidable within the body 55 of the syringe case 50 such that the cavity 61 is of variable volume.

Near the front end of the neck 59 of the syringe case 50, just behind the orifice 60, is an external thread 66 configured to mate with threads 67 on the interior of collar 52 (FIG. 3). The thread 66 in the neck 59 has a stop 69 at near forward end thereof to engage an abrupt step 70 on the thread 67 of the collar 52 so that, when the syringe 32 is properly oriented in the jacket 31, the collar 52, when loosened to its maximum extent, will assume a predetermined orientation so as to present, in an upwardly facing orientation, a tube end receiving slot 62 formed in the remote end of the collar 52. This slot 62 is of T-shaped cross-section so as to receive the enlarged flange end 63 of a tube 65 through which fluid from the syringe cavity 61 is injected into a patient.

The cap 51 is generally conical in shape and has an inner rearward surface 75, which conforms to the front surface of the conical wall 57 of the case 50 of the syringe 32. In certain embodiments, the rearward conical surface 75 of the cap 51 may be bonded to the front surface of the conical wall 57 of the case 50 of the syringe 32, or it may be formed integrally therewith, molded from the same plastic material as the case 50 of the syringe 32. In the preferred and illustrated embodiment, the cap 51 is separate from the syringe body portion 55 and has a pair of holes or detents 76 into which fit a pair of projections 77 extending forwardly from and formed integrally on the outer surface of the conical wall 57 of the case 50 of the syringe 32. The cooperation of the pins or projections 77 with the holes or detents 76 prevent the cap from rotating with respect to the syringe case 50 when the cap 51 is mounted on the syringe 32.

To hold the cap 51 against the conical wall 57 of the case 50 of the syringe 32, six resilient tabs 78 are formed about a central inner hole 79 of the cap 51. The tabs 78 are separated by six equally spaced radial slots 80 (FIG. 3). The hole 79 in the cap 51 is equal to or only slightly greater in size than the circular forward end of the conical wall 57 of the case 50 of the syringe 32. The neck 59 of the syringe 32 has an enlarged straight section 81 slightly greater in diameter than the hole 79 in the cap 51 and also greater in diameter than the forward end of the conical wall 57 of the case 50, thereby forming a groove 82 at the juncture of the straight neck portion 81 with the conical wall 57 so that the tips of the tabs 78, which are sufficiently resilient to slide over the enlarged neck portion 81 as the cap 51 is inserted on the case 50 of the syringe 32 with the hole 79 surrounding the neck 59 to snap fit into the groove 82.

The syringe 32 includes structure that is configured to lock the syringe 32 to the front end of the jacket 31 by cooperating with mating structure on the jacket 31. The jacket 31 has, spaced around the circumference thereof near the remote or front end 35 of the jacket 31, four equally spaced outwardly projecting thread sections 85. These thread sections 85 are slightly less than 45° in extension around the circumference of the jacket 31 and are spaced apart with gaps of slightly greater than 45°. The cap 51 has a cylindrical rim 87 in which are formed four similarly sized and spaced mating thread sections 86. The thread sections 86 project inwardly toward the jacket 31 when the syringe 32 is positioned in the jacket 31. As such, when the syringe 32, with the cap 51 assembled to it is inserted into the jacket 31, the threads 86 of the cap 51 pass through the spaces between the threads 85 on the jacket 31 to a point behind the threads 85. When so inserted, the syringe assembly 32 with the cap 51 may be twisted clockwise 45° to tighten and thereby secure the cap 51 to the jacket 31 by engagement between the threads 85 and 86 as shown in FIG. 5, to thereby lock the syringe in the bore 33.

The piston 54 of the syringe 32 is molded of an elastomeric material. Preferably, the piston 54 includes two portions molded of different materials and bonded together. These portions include a forward more flexible portion 90 in which is formed the forward conical surface 64. This forward portion 90 has a pair of outwardly extending rings 91 formed in the periphery thereof to make sealing engagement

with the inside of the wall of the cylindrical body **55** of the syringe case **50**. The rearward portion of the piston **54** is a flat circular surface to which is bonded the flat circular forward surface of a more rigid rear portion **93** of the piston **54**. The rear rigid portion **93** of the piston **54** is molded of a harder stronger plastic material and has a rearward facing circular surface **95** having a rearward extending coupling **96** integrally formed thereon at its center. The coupling **96** includes a rearwardly extending cylindrical shaft **97** on the axis **41** of the syringe **32** and a larger symmetrical cylindrical button **98** integrally formed at the rear end of the cylindrical shaft **97**.

Referring to FIG. **10**, a piston drive assembly **100** is illustrated contained within the housing **21**. The drive assembly **100** includes an electric motor **101** mounted within the fixed housing **21** and having a rotary output shaft **102** with a drive gear **103** fixed to the remote end thereof. The drive gear **103** is positioned for driving engagement with a driven gear **104** fixed near the rear end of a drive screw or shaft **105** supported at its rear end in a bearing **106** fixed in the housing **21**. The screw or shaft **105** has a continuous external helical thread **107** thereon which mates with interior threads of a carriage **108**. The carriage **108** is slidably supported in a bushing **109** fixed in the housing **21**. The shaft **105** rotates within the housing **21** about a longitudinal axis **112**.

At the forward end of the carriage **108** is supported a pair of hooked jaws **114** which are pivotally mounted at their rearward ends by a pair of pivot pins **115** to the carriage **108**. The jaws **114** are biased toward the axis **112** by a pair of balls **116***a* and **116***b* of resilient material positioned between the outside of the jaws **114** and an inner cylindrical wall **117** of a recess **118** formed in the forward end of the carriage **108**. The balls **116***a*, **116***b* are partially captured in depressions in the outer surfaces of the jaws **114**. The balls **116***a*, **116***b* bias the jaws toward their innermost position toward the axis **112**. The innermost position of the jaws is determined by a spacing block **119** on the axis **112** of the carriage **108** at the center of the cavity **118**.

When a syringe **32** is locked in the jacket **31** with its axis **41** and the axis **40** of the jacket **31** may be in alignment with the axis **112** of the shaft **105**, the plunger **54** may be located in the cylindrical body **55** of the syringe case **50** in a position forward of the remote end **56**. Preferably, however, the jaws **114** are displaced to the side of axis **112** of the shaft **105** so that as the jaws **114** and coupling tip **98** are in their disengagement position, maximum clearance is provided so that the syringe **32** may be inserted into the jacket **31** without the sterile internal walls of the syringe **31** touching the components of the drive, as illustrated in the figures.

In the engaging position, the jaws **114** are nonetheless in alignment with the coupling **98** on the axes **40** and **41** of the jacket **31** and syringe **32**. In such a situation, the jaws **114** may be in a retracted position at the center of the opening **39** of the door **25** adjacent to the proximate end **34** of the jacket **31**, and out of engagement with the coupling **96** on the plunger **54**. From this position, operation of the motor **101** rotates the shaft **105** and drives the carriage **108** forwardly to move the jaws **114** toward and into engagement with the coupling **96** on the plunger **54**. This engagement takes place as shown in FIG. **11** where a pair of tapered cam surfaces **120** at the forward interface of the tips of the jaws **114** engage the enlarged portion or button **98** of the coupling **96** to expand the jaws, as shown in FIG. **11**, to snap around the button **98** of the coupling **96** to form a driving engagement between the drive assembly **100** and the coupling **96** of the plunger **54** as shown in FIG. **12**. Once so engaged, any forward or reverse movement of the carriage **108** under the power of the motor **101** will cause the plunger **54** to be driven either forwardly or backwardly in the syringe body **55**.

Disengagement of the jaws **114** from the coupling **96** can thereafter be achieved by translational movement between the coupling **96** and the jaws **114** between a disengaged position as shown in FIG. **4** and an engaged position as shown in FIG. **5**. When the plunger coupling **96** and the jaws **114** are disengaged, the syringe **32** can be replaced without the need to retract the carriage **108** of the drive **100**. This allows for rapid replacement of the syringe **32**. Preferably, the jaws **114** are either fully retracted toward the housing **21** where engagement by translation of the coupling **96** will occur, or the jaws **114** are sufficiently within the jacket prior to replacement of the syringe so that the coupling **96** of the replacement syringe **32** will not contact the jaws **114** except as the drive **100** is advanced.

If sterility is not a problem, the most time saving approach would be to insert the syringe **32** into the jacket **31** with its plunger all the way forward and the drive fully advanced so that, when the syringe is translated toward the jaws **114**, engagement will immediately occur and the plunger can be immediately retracted to fill the syringe.

When a syringe **32** is inserted into the jacket **31** when the plunger **54** is at its rearmost position toward the proximate end **56** of the syringe body **55**, the coupling **96** is in a position adjacent the proximate end **56** of the syringe body **55** and projecting rearwardly therebeyond. When in such a position, engagement between the jaws and the coupling **96** is brought about by translational movement between the position shown in FIG. **4** and that shown in FIG. **5**. In the unlocked or disengaged position shown in FIG. **4**, the axes **40** and **41** of the jacket **31** and the syringe **32**, respectively, as well as the center of the opening **39** of the door **25**, lie spaced from and parallel to the axis **112** of the shaft **105** as shown in FIG. **4**. In the locked or engaged position, the axis **112** of the shaft **105** is slightly eccentric relative to the axes **40** and **41** of the jacket **31** and syringe **32**, respectively, as shown in FIG. **5**. This translational movement, the engagement and disengagement between the coupling **96** and the jaws **114** and the 45° rotational movement which secures the cap **51** to the pressure jacket **31** by engagement of the threads **85** and **86** are brought about by operation of a translating and locking mechanism **125**, which is best understood by reference to FIGS. **2–9**.

The translating and locking mechanism **125** includes a cam and locking ring **127** which is rotatably retained in a circular recess **126** in the back of the door **25**. The ring **127** has a generally semi-circular groove **130** in the back surface thereof for receiving a spring wire retaining clip **131** having a pair of looped ends **133** which extend through a pair of slots **134** in the rim of the ring **127** and into a selected one of three pair of diametrically opposed notches **135**, **136** and **137** in the inner wall of the rim of the recess **126** in the door **25**. The three pair of notches **135**, **136** and **137** represent three positions of the translating and locking mechanism **125** which are the locked, unlocked and release positions, respectively. The locked position of the mechanism **125** in which the loops **133** of the ring **131** are in the notches **135**, is that illustrated in FIGS. **5–7** and **10**. The unlocked position, in which the loops **133** of the ring **131** are in the notches **136**, is that illustrated in FIGS. **2–4** and **8**. The release position, in which the loops **135** of the clip **133** are in notches **137**, is that illustrated in FIG. **9**. The ring **127** is moved among these three positions by a manually accessible handle **138** in the form of a cylindrical knob **139** rotatably

attached to a lever arm 140 formed integrally and extending radially from the ring 127 through a slot 141 in the door 25 (FIG. 2). The ring 127 is retained in the recess 126 by a pair of screws 143 which thread into countersunk holes 144 at the periphery of the recess 126 in the back of the door 25. These screws 143 have enlarged heads 146, which, when seated in the holes 144, overlie the edge of the ring 127, thereby securing it for rotatable movement within the recess 126.

As shown in FIGS. 2 and 6, the ring 127 has an inner periphery 149 which is larger than the circumference of the body 55 of the syringe case 50. Accordingly, when the syringe 32 is inserted in the jacket 31, the proximate end 56 of the syringe case 50 extends through and is surrounded by the inner periphery 149 of the ring 127. Asymmetric keyway structure, preferably in the form of three slots or notches 151, 152 and 153 (FIG. 6) are provided in the edge of the proximate end 56 of the body 55 of the syringe case 50. The spacings between adjacent pairs of the notches 151–153 differ from each other. Formed integrally of the ring 127 and projecting inwardly from the inner periphery 149 thereof are three tabs or keys 155, 156 and 157. These tabs 155–157 are spaced so as to fit into the respective notches 151–153 in the proximate end 56 of the body 55 of the syringe case 50 so as to rotate the syringe 32 as the mechanism 125 is rotated through actuation of the handle 138. Because the notches 151–153 and the tabs 155–157 are unequally spaced, they can only engage each other when the syringe 32 is inserted into the jacket 31 in one and only one orientation. That orientation is one which will cause the slot 62 of the collar 52 (FIG. 3) to align 45° counterclockwise of the vertical when the mechanism 125 is in its unlocked position, which is a position in which it will be when the syringe is first inserted into the jacket 31, and to be in an upwardly facing orientation, when fully loosened, when the mechanism 125 is moved to its locked position. Accordingly, the notches 135 and 136 in the recess 126, which receive the loops 133 of the spring clip 131 when respectively in the locked and unlocked positions, are 45° apart.

The rotation of the mechanism 125 from the unlocked position to the locked position rotates the syringe 32 in the jacket 31 and rotates the cap such that its threads move from an unlocked position as shown in FIG. 4 to the locked position of FIG. 5, to secure the cap to the jacket 31 by the engagement and tightening of the threads 85 and 86.

The translational movement of the axes 40 and 41 with respect to the axis 112 is achieved by a fixed cylindrical cam follower or pin 150 which projects outwardly from the fixed housing portion 22 behind the ring 127 and into a cam slot 154 formed therein. The slot 154 is shaped so that the axes 40 and 41 which remain fixed with respect to the ring 127, along with the door 25, the jacket 31, the syringe 32 and all of the structure mutually carried thereby, are moved in relation to the axis 112 of the shaft 105 and the other structure mutually carried by the housing 21, as the mechanism 125 is rotated. These axes move toward and away from each other in accordance with the shape of the slot 154 determined by the radial distance from the point along the slot 154 where it engages the pin 150 to the axes 40 and 41.

The cam slot 154 in the ring 127 is shaped such that, when the mechanism 125 is in the locked position as shown, for example, in FIGS. 6 and 7, the distance between the pin 150 and the axes 40 and 41 is at a minimum and the axis 112 coincides with the axes 40 and 41. This is illustrated in FIGS. 5 and 7 wherein the coupling 96 is shown positioned between the jaws 114 and in mutual engagement therewith. When the mechanism 125 is in the unlocked position, with the loops 133 of clip 131 in the notches 135 (FIG. 6) of the recess 126, the pin 150 lies in the slot 154 in the position shown in FIG. 8, which is farther displaced from the axes 40 and 41 than in the position of FIGS. 6 and 7, so that the coupling 96 is translated to a position outside of the center line of the jaws 114, as shown in FIG. 8 and further illustrated in FIG. 4.

In the release position, as shown in FIG. 9, the pin 150 is positioned at the open end 160 of the cam surface of the slot 154 so that the door 25 can be rotated upwardly about the hinge pin 26, as shown in FIG. 9, to open the space behind the door 25 for access thereto. This position may be used for cleaning the area behind the door 25 which is sometimes necessary because of possible leakage of fluid from the cavity 61 into the space behind the plunger 54. This can possibly occur because the fluid within the cavity 61, when being injected by forward advancement of the plunger 54, may be of relatively high pressure in the range, usually over 200 psi. For applications such as the injection of contrasting fluid for CT scanning, pressure may typically be in the range of from 25 to 300 psi., while in some angiographic injection applications the pressure may range to 1200 psi or higher.

In addition, leakage rearwardly along the exterior of the neck 59 of the syringe 32 can cause fluid to flow between the body portion 55 of the syringe 32 and the jacket 31. For this reason, the cap 51 is caused to fit snugly against the forward surface of the conical portion 57 of the syringe 32 at least sufficiently to restrict the flow of this leaking fluid onto the neck 59. This is assisted by the configuration of the cap 51 at the rim 87 thereof so as to divert away from the space between the syringe 32 and jacket 31 fluid which might leak from the nozzle.

The front of the housing 21 has formed thereon a door stop 185 having a slot 186 formed therein for receiving a lug 187 of the door 25, to restrain the door 25 against forward force exerted by the drive 100. Behind the front of the housing 21 adjacent the stop 185 is a magnetic sensor 188, which is responsive to the presence of a magnet 189 in the lever arm 139 of the handle 138. The sensor 188 generates a signal to the control module 16 to activate the drive 100 only when the mechanism 125 is in its locked position.

Referring to FIG. 13, there is illustrated a locking mechanism 225 that is an alternative to the locking mechanism 125 described above. In the locking mechanism 225, a stationary geared rack 250 is provided fixed to the housing 21. A mating gear segment 254 is formed on the outer rim of the alternative locking ring 227 of this embodiment. The gear segment 254 and rack 250 replace and function in the same way as the slot 154 and pin 150 of the embodiment described above. As the mechanism 225 is rotated by the handle 138, the door 25 that carries the jacket 31 and the syringe 32 is translated to bring the coupling 96 into or out of engagement with the jaws 114 of the drive 100. Simultaneous with this translatory motion, the syringe 32 is rotated in the jacket 31 to lock or unlock the syringe 32 to the jacket 31 by engagement or disengagement of the threads 86 on the syringe 32 with the threads 85 on the jacket 32.

FIG. 14 illustrates an alternative to the embodiment of the coupling 96 described above. In the embodiment of FIG. 14, there is provided a coupling 296 that is T-shaped, having a rectangular endpiece 298 at the rearward end of a cylindrical or square shaft 297 on the rearwardly facing circular surface 95 of the plunger 54. Such a coupling 296 engages the jaws 114 by rotation of the locking mechanism 125 or 225, preferably through an angle of 90°. When the orientation of the endpiece 298 is parallel to the plane of the jaws 114, the drive 100 is locked to the plunger 54 so that axial movement

of the drive **100** moves the plunger axially, in the forward direction to expel fluid form the syringe cavity **61**, or in a rearward direction to fill the cavity **61** with fluid. When the endpiece **298** is perpendicular to the plane of the jaws **114**, the coupling **296** will move into or out of engagement with the jaws **114** upon relative axial movement between the plunger **54** and the drive **100**. Thus, with this embodiment, rotational motion, rather than translational motion, causes engagement and disengagement of the coupling **296** by the jaws **114**. With this embodiment, orientation of the syringe **32**, when loaded into the jacket **31**, is preferably maintained through the cooperation of the notches **151–153** and the tabs **154–156** (FIG. **4**), so that the coupling **296** will enter the jaws **114**, when the syringe **32** is inserted into the jacket **31**, with the endpiece **298** perpendicular to the pair of jaws **114**.

The locking structure between the syringe **32** and the pressure jacket **31** should provide for retention of the syringe **32** in the jacket **31** against the force of the fluid pressure in the cavity **61** or axial force otherwise exerted on the plunger **54** by the drive **100**. This locking of the syringe **32** to the jacket **31** is preferably achieved, as shown in FIG. **5**, by structure at or near the forward wall **57** of the syringe case **50**. In accordance with the embodiment of FIG. **15**, such structure may include external threads **200** formed of four equally spaced, radially outwardly directed thread sections (flanges), each spanning slightly less than 45° about syringe body **257**, and positioned (monolithic with) the forward end of the syringe body **257**, which mate with internal threads **201** formed of four equally spaced, radially inwardly directed mating thread sections (flangs), each spanning slightly less than 45° about jacket **31**, positioned around the opening at the remote end of the tubular cylindrical pressure jacket **31**. With such an embodiment, the syringe **32** is preferably provided with continuous, planar annular ring-shaped flange **203** around (monolithic with) the body **257** at the juncture of the body **257** with the syringe front wall **258**. Threads **200** and **201** form a connector, specifically, a screw or twist lock whereby syringe **32** may be rotated or twisted 45° to lock syringe **32** to the injector. The flange **203** inhibits the flow of leaked fluid into the space between the syringe body **257** and a peripheral rim of the jacket **31**. With such an embodiment, the wall **258** is either thickened, provided with reinforcing such as the ribs **208**, or provided with other structure to resist deformation of the wall **258** under the pressure of the fluid within the cavity **61**.

Alternatively, a reusable split clip **210** may be employed to secure a continuous flange **203** of such a syringe to a continuous flange **212** at the end of the pressure jacket in the embodiment of FIG. **16**. As a further alternative as shown in FIG. **17**, a ring clip **210***a* having an outer rim **215** and rotatably mounted to the jacket **31**, encircles and engages outwardly projecting threads **203***a* of a disk flange **213** formed at the front end of the syringe **32** to engage the jacket in a manner similar to the threads **85** and **86** in the embodiment of FIGS. **2–12** above.

The invention has been described in the context of its preferred embodiments. It will be appreciated by those skilled in the art that variations and alternatives to the embodiments described may be employed without departing from the principles of the present invention. Accordingly, this patent is not intended to be limited except by the scope of the following claims:

We claim:

1. A disposable replacement syringe for a front loadable injector for injecting liquid into an animal, where the injector has a syringe receiving opening on the front thereof and has a plurality of internal sections circumferentially displaced inside the opening, the disposable syringe comprising:

a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, and an open rearward end;

a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon;

an annular flange extending outwardly from the hollow body and monolithic therewith, the annular flange lying in a plane perpendicular to the longitudinal axis of the body; and

locking structure spaced longitudinally a fixed distance rearwardly from the annular flange monolithic with and extending radially from the tubular wall of the body a distance smaller than the outward extension of said annular flange, the locking structure being in the form of a plurality of circumferentially spaced radially extending mating sections configured to engage the internal sections inside the opening on the front of the injector to lock the syringe thereto upon the rearward longitudinal insertion of the mating sections through the opening and the partial rotation of the syringe in the opening, and to thereby urge the annular flange against the opening.

2. The disposable replacement syringe of claim **1** for use with an injector having a pressure jacket extending forwardly therefrom, the jacket having a cylindrical bore therein, the opening of the injector being the hollow bore of the jacket, and wherein the internal internal sections are fixedly located on the inside of the jacket, wherein:

the radially extending mating sections of the locking structure comprise mating sections positioned in a plane perpendicular to the axis of the body of the syringe so as to align with the internal sections on the jacket when the syringe is inserted in the jacket and to lock the syringe to the jacket.

3. The disposable replacement syringe of claim **2**, wherein:

the annular flange is in the form of a continuous annular ring surrounding the body; and

the locking structure forms means for sealably urging the annular flange against the jacket when the syringe is locked to the jacket to inhibit leakage of spilled fluid into the injector.

4. The disposable replacement syringe of claim **1**, wherein:

the annular flange extends outwardly from the forward end of the hollow body.

5. The disposable replacement syringe of claim **1**, wherein:

the locking structure extends radially outwardly from the tubular wall adjacent the forward end of the hollow body.

6. The disposable replacement syringe of claim **1**, wherein:

the plurality of radially extending mating sections includes four equally spaced sections lockable to the internal sections upon rotation of 45 degrees about the axis.

7. The disposable replacement syringe of claim **1**, wherein:

the plurality of radially extending mating sections includes four equally spaced sections each spanning not more than 45 degrees about the axis.

8. The syringe of claim **1**, for use with an injector having a tubular member extending forwardly from the front thereof

and having a cylindrical bore therein forming the opening at the front of the injector, the tubular member having a circular front end lying in a plane; and further comprising:

means, including the locking structure, for urging the annular flange rearwardly against the front end of the tubular member.

9. The syringe of claim 1 for use with an injector having a continuous rim surrounding and forming the periphery of the opening, and wherein:

the annular flange is in the form of a continuous annular ring; and

the locking structure urges the annular flange rearwardly against the syringe receiving opening when the syringe is locked to the injector to form a seal with the opening to inhibit leakage of spilled fluid into the injector.

10. The disposable replacement syringe of claim 1, wherein:

the plurality of radially extending mating sections includes spaced thread sections each spanning not more than 45 degrees.

11. A disposable replacement syringe for a front loadable injector for injecting liquid into an animal where the injector has a circular syringe receiving opening therein bounded by a circular annular periphery lying in a plane and syringe-retaining structure spaced a fixed distance rearward of the periphery and positioned relative to the opening to be engageable therethrough, the disposable syringe comprising:

a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, and an open rearward end;

a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon;

a planar annular ring surrounding, extending outwardly from and monolithic with the cylindrical tubular wall forward of the rearward end of the body and lying in a plane perpendicular to the longitudinal axis of the body;

the ring having a rearward facing planar annular surface dimensioned to overly the periphery of the opening; and

locking structure monolithic with the tubular wall of the syringe and extending radially therefrom a distance smaller than the outward extension of said annular ring, spaced the fixed distance rearward of the ring and dimensioned to fit through the opening so as to engage the syringe retaining structure of the injector and urge the ring to seal against the periphery of the opening on the injector to inhibit leakage of spilled fluid into the injector.

12. The disposable replacement syringe of claim 11 wherein:

the locking structure is configured to secure the syringe to the injector by engaging the syringe retaining structure on the injector with a twisting motion to sealably urge the ring against the periphery of the circular opening.

13. The disposable replacement syringe of claim 12 wherein:

the locking structure includes a plurality of circumferentially spaced sections configured to engage the syringe retaining structure of the injector around the opening on the injector to lock the syringe thereto upon rearward longitudinal insertion of the syringe into the opening and partial rotational motion of the syringe.

14. The disposable replacement syringe of claim 11 further comprising:

an annular split clip configured to secure the syringe to the injector; and wherein:

the ring has a diameter substantially equal to a diameter of said split clip to facilitate engagement by the split clip to lock the syringe to the injector and to urge the ring against the periphery of the circular opening.

15. A disposable replacement syringe for a front loadable injector having a syringe receiving opening thereon, the disposable syringe comprising:

a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, and an open rearward end;

a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon;

a planar annular ring-shaped flange surrounding, monolithic with and extending outwardly from the hollow body and perpendicular to the longitudinal axis of the body; and

a connector monolithic with the body having an outer breadth smaller than the outward extension of said annular ring-shaped flange, spaced longitudinally rearwardly from the annular ring-shaped flange for locking the syringe to the opening on the injector upon the rearward longitudinal insertion of the rearward end of the syringe into the opening and for sealably urging the annular ring-shaped flange rearwardly against the periphery of the opening to inhibit leakage of spilled fluid into the injector.

16. The syringe of claim 15 wherein the connector includes screw threads in the form of a plurality of circumferentially spaced flange sections extending radially outwardly from the tubular wall to cooperate with mating threads on the injector.

17. The syringe of claim 16 wherein:

the screw threads include four flange sections each spanning less than the circumference of the body so as to enable threaded engagement with the mating threads upon 45° rotation of the syringe.

18. A front loadable power injector for injecting liquid into an animal comprising:

an injector having a housing, a syringe receiving opening and a plunger driving ram mounted in the housing and extendable along an axis through the opening;

a syringe having a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, an annular flange monolithic therewith extending around and outwardly from the hollow body and perpendicular to the longitudinal axis of the body, and locking structure monolithic therewith spaced longitudinally rearwardly from the annular flange and extending radially from the tubular wall of the body a distance smaller than the outward extension of said annular flange;

the locking structure being in the form of a plurality of circumferentially spaced radially extending sections;

the injector having a plurality of circumferentially spaced radially extending mating sections spaced around the opening;

the radially extending sections of the locking structure being sized to fit between the radially extending mating sections at the opening so as to lock the syringe to the injector upon the rearward longitudinal insertion of the radially extending sections of the locking structure into the opening and between the radially extending mating sections at the opening, followed by partial rotation of the syringe in the opening to thereby urge the annular flange against the opening.

19. The injector of claim 18 wherein:

the injector has a pressure jacket extending forwardly from the housing, the jacket having a cylindrical bore therein, the syringe receiving opening of the injector being in the bore of the jacket; and

the mating sections at the opening are fixedly located on the jacket, whereby the radially extending sections of the locking structure lock the syringe to the jacket.

20. The injector of claim 19 further comprising:

means including the locking structure and the mating sections for sealably urging the annular flange against the jacket.

21. The injector of claim 20 wherein:

the jacket has a circular front end lying in a plane; and

the annular flange is sealably urged rearwardly against the front end of the jacket.

22. The injector claim 18 wherein:

the annular flange is in the form of a continuous annular ring lying in a plane and surrounding the hollow body; and

the ring is configured such that, when urged against the opening, a seal is formed to inhibit leakage of spilled fluid into the injector.

23. The injector claim 18 wherein:

the annular flange extends outwardly from the forward end of the hollow body; and

the injector includes a cylindrical member extending forwardly from the injector housing and having a hollow bore therethrough, the syringe receiving opening being at an end of the bore remote from the injector housing.

24. The injector of claim 18 wherein:

the locking structure extends radially outwardly from the tubular wall adjacent the forward end of the hollow body of the syringe.

25. The injector of claim 18 wherein:

the plurality of radially extending sections of the locking structure and the mating sections at the opening each include four equally spaced thread sections; and

the sections are configured to mutually engage upon rotation of the syringe of 45 degrees.

26. The injector of claim 18 wherein:

the plurality of radially extending sections of the locking structure and the mating sections at the opening each include four equally spaced thread sections spanning not more than 45 degrees.

27. The injector of claim 18 wherein:

the injector housing has a tubular member extending forwardly from the front thereof and having a cylindrical bore therein forming the syringe receiving opening;

the tubular member has a circular front end lying in a plane; and

the annular flange is sealably urged rearwardly against the front end of the tubular member.

28. The injector of claim 18 wherein:

the plurality of outwardly extending sections of the locking structure and the plurality of radially extending mating sections at the opening each include equally spaced thread sections; and

the sections are configured to mutually engage upon rotation of the syringe of 45 degrees.

29. The injector of claim 18 wherein:

the plurality of radially extending sections of the locking structure and the plurality of radially extending mating sections at the opening each include equally spaced thread sections spanning not more than 45 degrees.

30. A front loadable injector for injecting liquid into an animal comprising:

an injector housing having a circular syringe receiving opening bounded by a circular annular periphery lying in a plane and syringe retaining structure spaced a fixed distance rearward of the periphery of the opening and positioned relative to the opening to be engagable therethrough;

a plunger driving ram mounted in the housing and extendable along an axis through the opening;

a syringe having a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, and a planar annular ring surrounding and extending outwardly from the cylindrical tubular wall, spaced forward of the rearward end and lying in a plane perpendicular to the longitudinal axis of the body;

the ring of the syringe being monolithic with the tubular wall of the syringe and having a rearward facing planar annular surface dimensioned to overly the periphery of the opening; and

the syringe having locking structure thereon monolithic with the tubular wall of the syringe and extending radially therefrom a distance smaller than the outward extension of said annular ring, spaced the fixed distance rearward of the ring and dimensioned to fit through the opening so as to engage the syringe retaining structure of the injector and urge the ring rearwardly to seal the syringe against the periphery of the circular opening on the injector to inhibit leakage of spilled fluid into the injector.

31. The injector of claim 30 wherein:

the locking structure on the syringe and the syringe retaining structure on the injector form a twist lock at least partially carried by the syringe and partially by the injector and configured to secure the syringe to the injector and to sealably urge the ring against the periphery of the circular opening.

32. The injector of claim 31 wherein:

the twist lock includes a plurality of circumferentially spaced thread sections including thread sections forming the locking structure on the syringe and mating thread sections forming the syringe retaining structure on the injector, the thread sections of the locking structure being configured to engage the thread sections of the syringe retaining structure inside the syringe receiving opening to lock the syringe to the injector upon rearward longitudinal insertion of the syringe into the opening and rotational motion of the syringe relative to the injector.

33. A front loadable injector for injecting liquid into an animal comprising:

an injector housing having a syringe receiving opening surrounded by a continuous flange;

a plunger driving ram mounted in the housing and extendable on an axis through the opening;

a syringe having a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, and a planar annular ring surrounding and extending outwardly from the cylindrical tubular wall, spaced forward of the rearward end and lying in a plane perpendicular to the longitudinal axis of the body;

the ring of the syringe being monolithic with the tubular wall of the syringe and having a rearward facing planar annular surface dimensioned to overly the flange that surrounds the opening to seal the syringe against the periphery of the opening on the injector to inhibit leakage of spilled fluid into the injector;

a reusable split clip configured to clip the ring of the syringe to the flange of the injector to secure the syringe to the injector to lock the syringe to the injector and to urge the ring against the flange surrounding the circular opening.

34. A front loadable injector for injecting liquid into an animal comprising:

an injector housing having a syringe receiving opening and a plunger driving ram mounted in the housing and extendable along an axis through the opening, the opening being bounded by a forward facing peripheral rim;

a syringe having a hollow body, the body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, and a flange monolithic with the body, extending outwardly from the hollow body and perpendicular to the longitudinal axis of the body, the flange having an annular rearwardly facing surface; and

a connector partially on the injector and partially on the syringe locking the syringe to the opening on the injector upon rearward longitudinal insertion of the rearward end of the syringe into the opening and urging the rearwardly facing surface of the flange against the peripheral rim of the opening to inhibit leakage of spilled fluid into the injector, the connector including locking structure monolithic with the body of the syringe having an outer breadth smaller than the outward extension of said flange and spaced a fixed distance rearward of the flange and mating structure on the injector within the opening spaced the fixed distance rearward of the peripheral rim of the opening.

35. The injector of claim 34 wherein the locking structure includes screw threads in the form of a plurality of circumferentially spaced thread sections extending outwardly from the tubular wall of the syringe and the mating structure includes a plurality of circumferentially spaced mating thread sections spaced around the opening on the injector.

36. The injector of claim 35 wherein:

the screw threads include thread sections each spanning less than the circumference of the body so as to enable threaded engagement with the mating threads upon 45° rotation of the syringe.

37. The injector of claim 34 wherein:

the flange is in the form of a continuous annular ring surrounding the tubular body at the forward end thereof, and the connector includes locking structure extending radially from the tubular wall and spaced rearwardly from the ring, urging the ring against the peripheral rim of the opening so as to form a seal therewith to inhibit leakage of spilled fluid from entering the injector.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,658,261

DATED : August 19, 1997

INVENTOR(S) : Neer et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4, Line 22, after the word "plunger", replace "cut" with --out--.

Column 10, Line 30, after the word "jaws", insert the number --114--.

Column 13, line 2, delete the word "form", replace it with --from--.

Column 13, line 25, after the word "positioned", insert the word --on--.

Column 14, line 29, Claim 2, delete the word "internal", first occurrence.

Column 17, line 27, Claim 22, after the word "injector", insert --of--.

Column 17, line 34, Claim 23, after the word "injector", insert --of--.

Signed and Sealed this

Twenty-fourth Day of March, 1998

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

US005662612A

United States Patent [19]

Niehoff

[11] Patent Number: 5,662,612

[45] Date of Patent: Sep. 2, 1997

[54] **CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS**

[75] Inventor: **Kenneth J. Niehoff**, Cincinnati, Ohio

[73] Assignee: **Liebel Flarsheim Company**, Cincinnati, Ohio

[21] Appl. No.: **494,795**

[22] Filed: **Jun. 26, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 157,823, Nov. 24, 1993, abandoned.

[51] **Int. Cl.**^{6} **A61M 37/00**

[52] **U.S. Cl.** **604/155**; 604/151; 417/15; 417/63

[58] **Field of Search** ..... 604/67, 131, 151, 604/154, 155; 417/15, 33, 42, 43, 44 J, 63

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,475,666	10/1984	Billbrey et al.	604/155
4,529,401	7/1985	Leslie et al.	604/155
4,685,903	8/1987	Cable et al.	604/151
4,722,734	2/1988	Kolin	604/151
4,741,732	5/1988	Crankshaw et al.	604/155
4,767,406	8/1988	Wadham et al.	604/67
4,854,324	8/1989	Hirshman et al.	604/155
4,978,335	12/1990	Arthur, III .	
4,988,337	1/1991	Ito	604/67
5,034,004	7/1991	Crankshaw .	
5,078,836	1/1992	Sancoff et al.	604/67
5,135,507	8/1992	Haber et al.	604/187
5,236,416	8/1993	McDaniel et al. .	
5,242,408	9/1993	Jhuboo et al.	604/67
5,256,157	10/1993	Samiotes et al.	604/67
5,342,298	8/1994	Michaels et al.	604/65
5,354,287	10/1994	Wacks	604/232
5,356,393	10/1994	Haber et al.	604/222
5,383,858	1/1995	Reilly et al.	604/152
5,425,716	6/1995	Kawasaki et al. .	

FOREIGN PATENT DOCUMENTS

160 303	11/1985	European Pat. Off. .	
164 904	12/1985	European Pat. Off. .	
364010	4/1990	European Pat. Off.	604/151
482 677	4/1992	European Pat. Off. .	
523 343	1/1993	European Pat. Off. .	
WO89/06145	1/1988	WIPO .	

OTHER PUBLICATIONS

Declaration of James H. Goethel.

Declaration of Kenneth J. Niehoff.

Medrad, Inc., "The First and Only True Injection System" Medrad Mark V System Brochure, 1988.

Dwayne Crawford, "Declaration of Dwayne Crawford".

Brochure for "Angiomat 6000" of Liebel–Flarsheim, 2111 E. Galbraith Rd., Cincinnati, OH 45215, copyright 1987.

Brochure for "Angiomat CT" of Liebel–Flarsheim, 2111 E. Galbraith Rd., Cincinnati, OH 45215, copyright 1988.

Brochure for "PercuPump 1A" of E–Z–EM, Inc., 717 Main St., Westbury, NY 11590, copyright 1990.

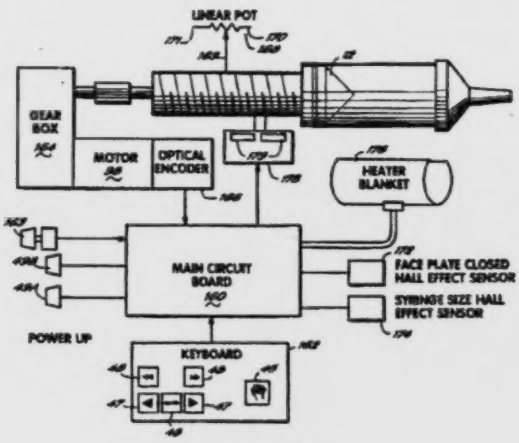
Primary Examiner—Todd E. Manahan

Attorney, Agent, or Firm—Wood, Herron & Evans, L.L.P.

[57] **ABSTRACT**

A computer-controlled injector of the type as a motor which advances and retracts a plunger located within a syringe housing toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject. The injector tracks the plunger position during an injection, and compensates for plunger extenders found in partially pre-filled syringes by applying a stored offset value to the computed plunger position, to produce a corrected plunger position reflecting the actual position of the plunger and compensating for the presence of the extender. The offset value can be determined by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value, or may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

12 Claims, 11 Drawing Sheets



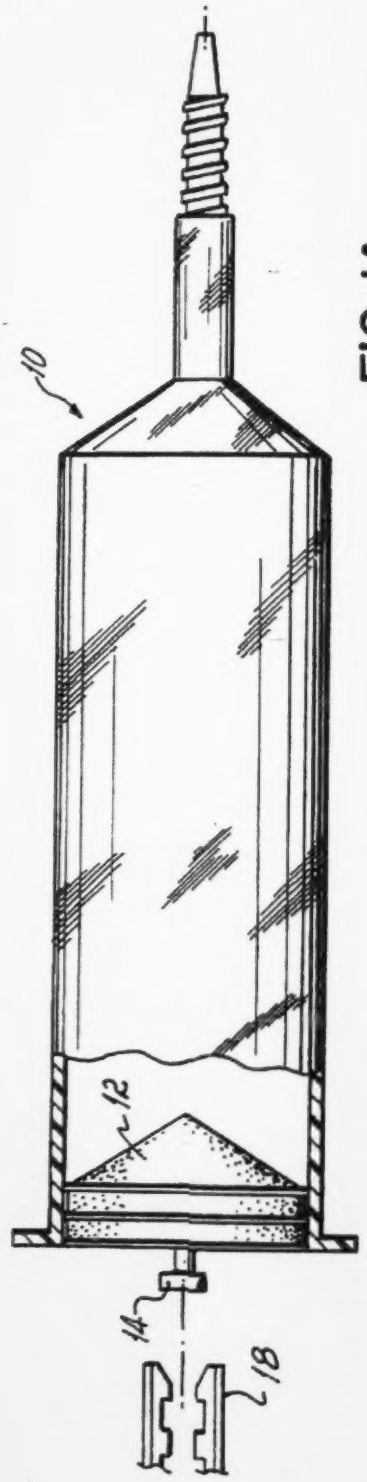


FIG. IA

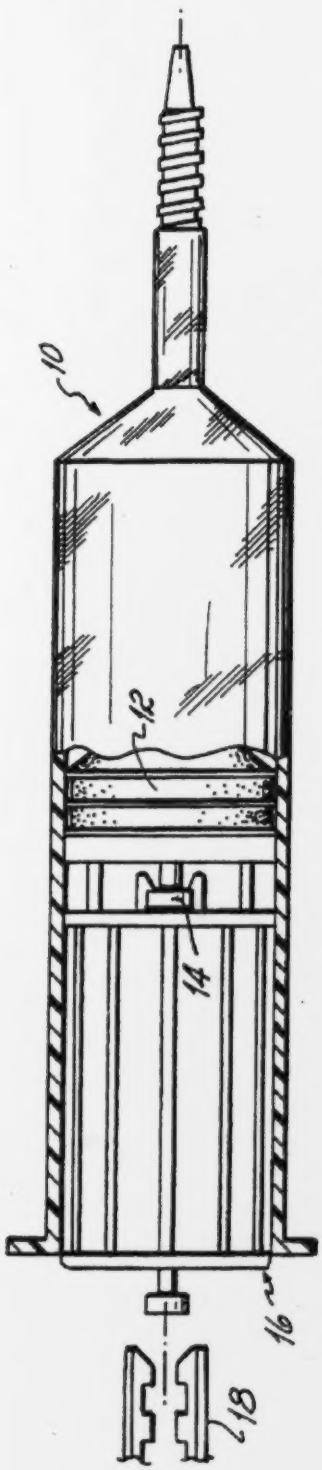


FIG.IB

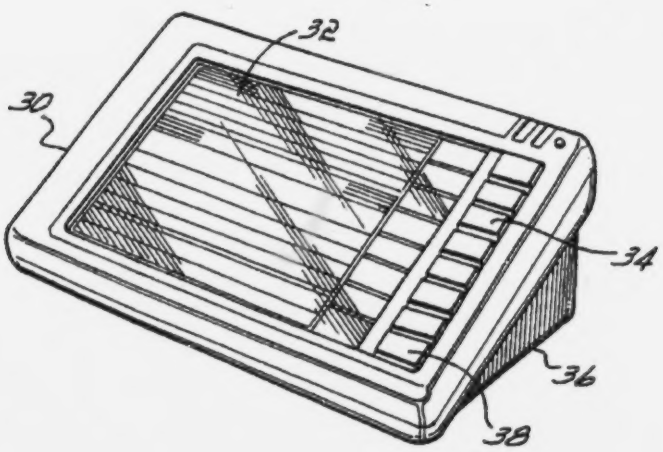


FIG. 2A

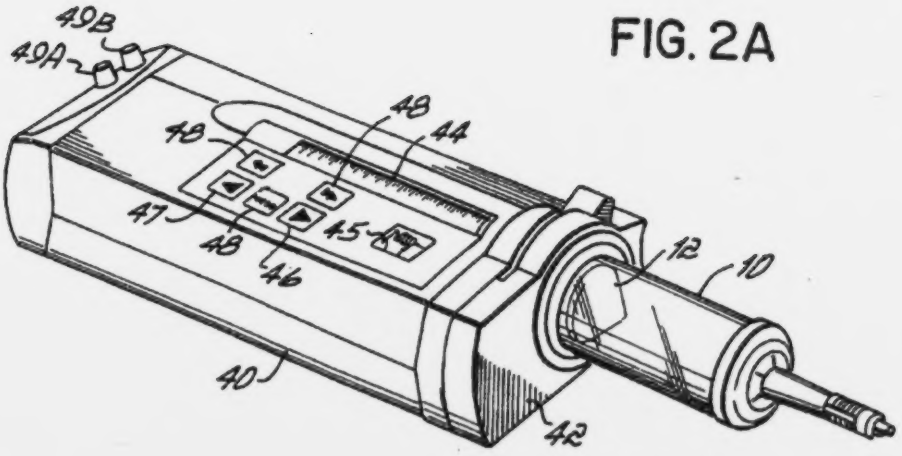


FIG. 2B

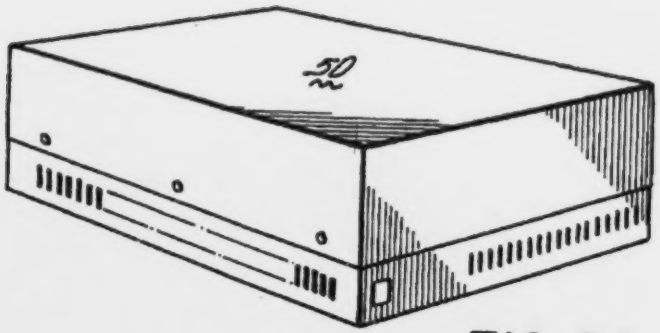


FIG. 2C

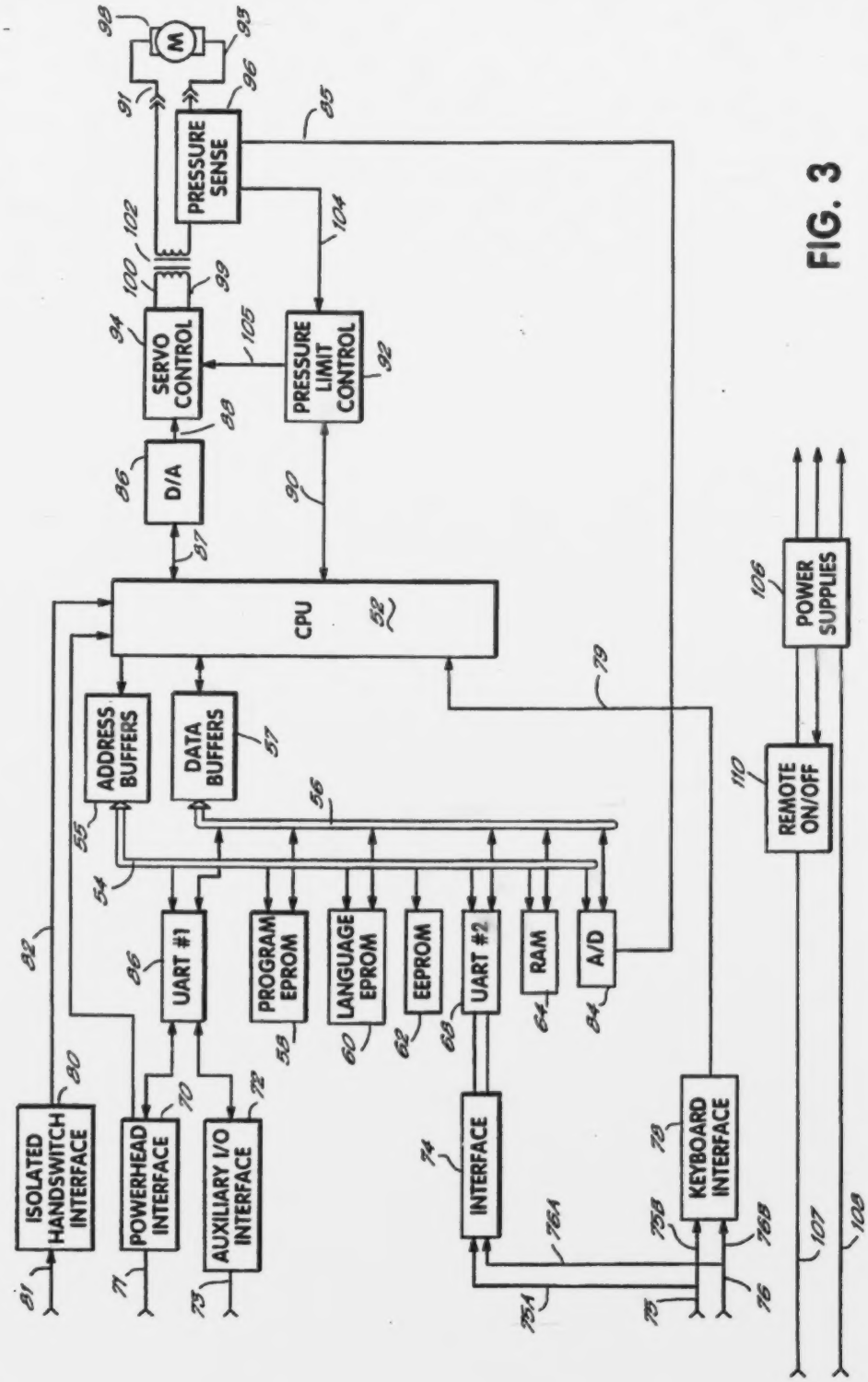

M
PRESSURE SENSE
SERVO CONTROL
PRESSURE LIMIT CONTROL
D/A
CPU
ADDRESS BUFFERS
DATA BUFFERS
UART #1
PROGRAM EPROM
LANGUAGE EPROM
EEPROM
UART #2
RAM
A/D
ISOLATED HANDSWITCH INTERFACE
POWERHEAD INTERFACE
AUXILIARY I/O INTERFACE
INTERFACE
KEYBOARD INTERFACE
POWER SUPPLIES
REMOTE ON/OFF

FIG. 3

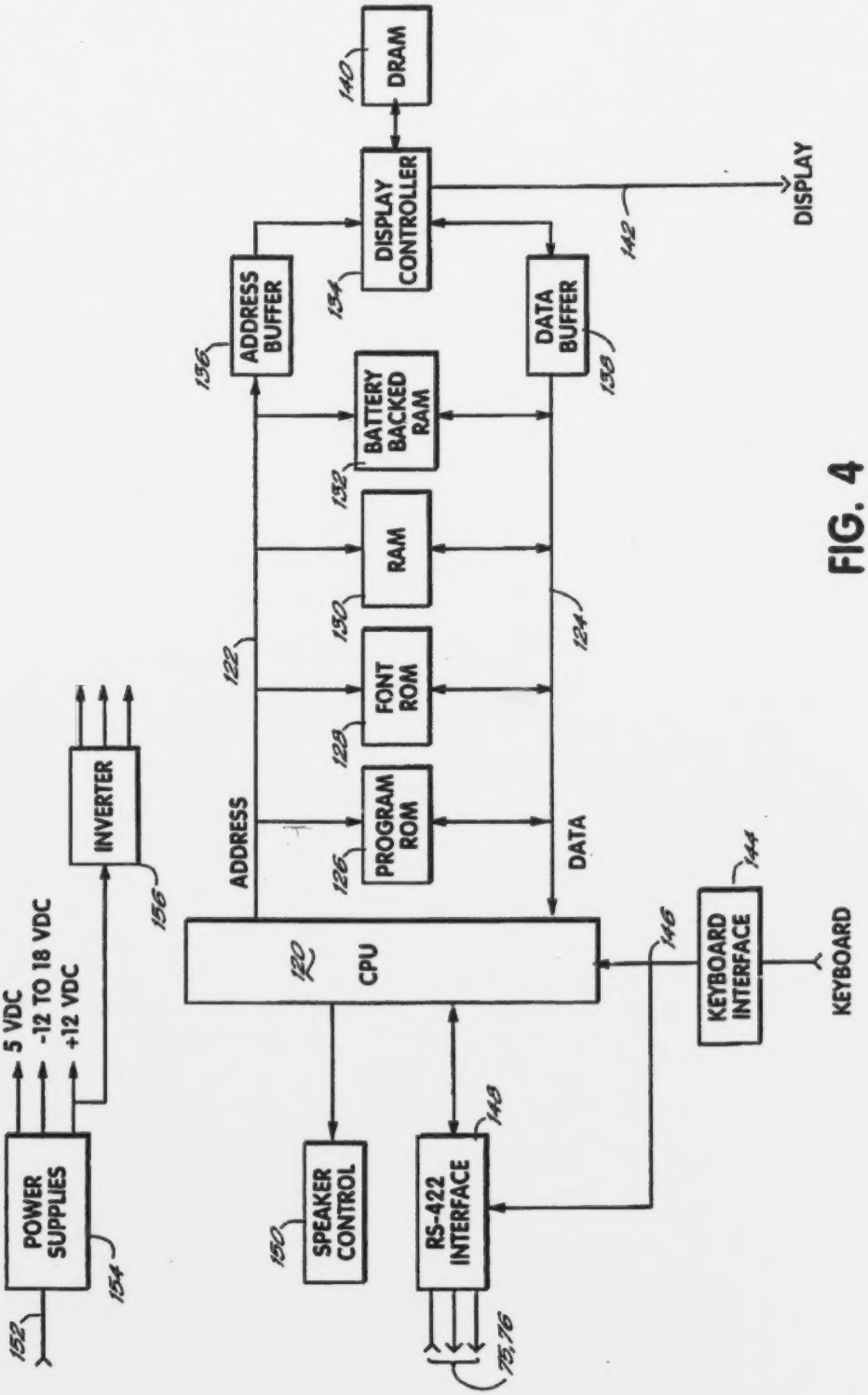

DRAM
140
DISPLAY CONTROLLER
154
DISPLAY
142
ADDRESS BUFFER
156
DATA BUFFER
158
BATTERY BACKED RAM
132
RAM
130
FONT ROM
128
PROGRAM ROM
126
ADDRESS
122
DATA
124
CPU
120
INVERTER
156
5 VDC
-12 TO 18 VDC
+12 VDC
POWER SUPPLIES
154
152
SPEAKER CONTROL
150
RS-422 INTERFACE
148
75,76
KEYBOARD INTERFACE
146
144
KEYBOARD

FIG. 4

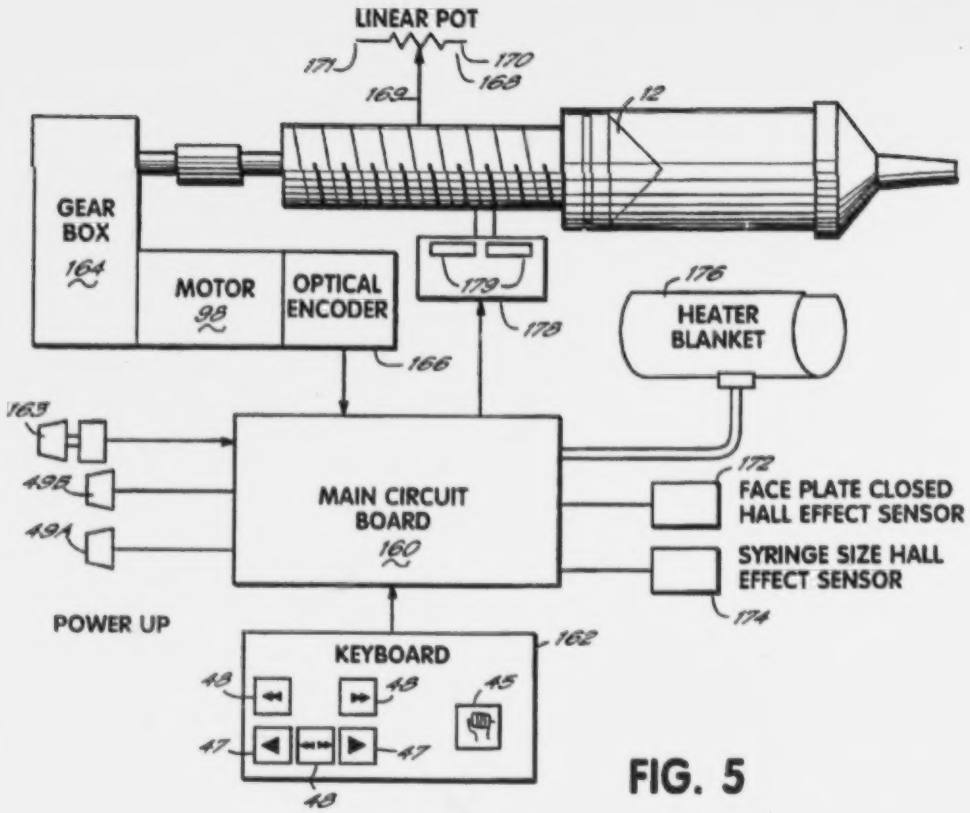

LINEAR POT
171
170
169
162
12
GEAR BOX
164
MOTOR
98
OPTICAL ENCODER
179
178
176
HEATER BLANKET
166
163
49B
49A
MAIN CIRCUIT BOARD
160
172
FACE PLATE CLOSED HALL EFFECT SENSOR
SYRINGE SIZE HALL EFFECT SENSOR
174
POWER UP
KEYBOARD
162
49
45
47
43

FIG. 5

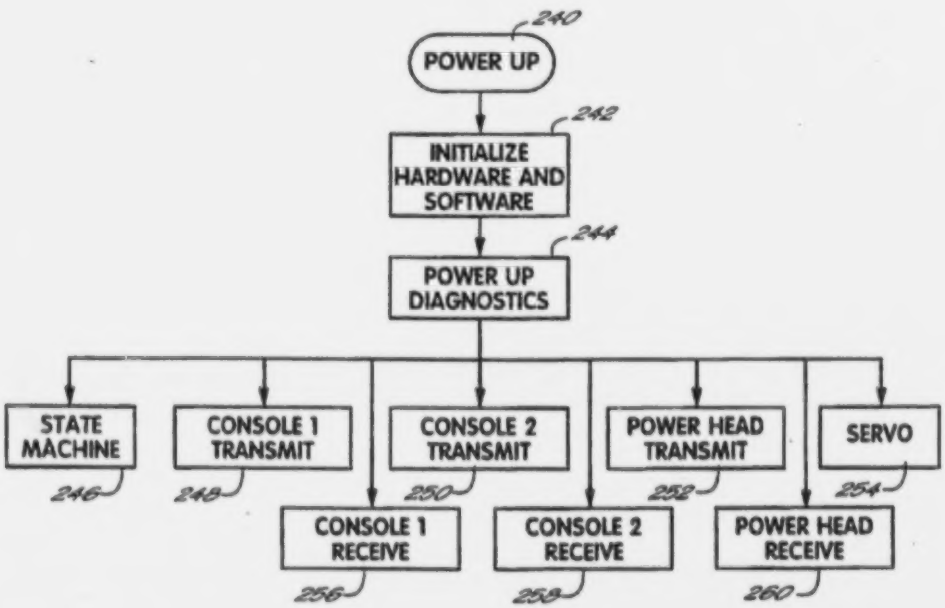

240
POWER UP
242
INITIALIZE HARDWARE AND SOFTWARE
244
POWER UP DIAGNOSTICS
STATE MACHINE
246
CONSOLE 1 TRANSMIT
248
CONSOLE 2 TRANSMIT
250
POWER HEAD TRANSMIT
252
SERVO
254
CONSOLE 1 RECEIVE
256
CONSOLE 2 RECEIVE
258
POWER HEAD RECEIVE
260

FIG.7A

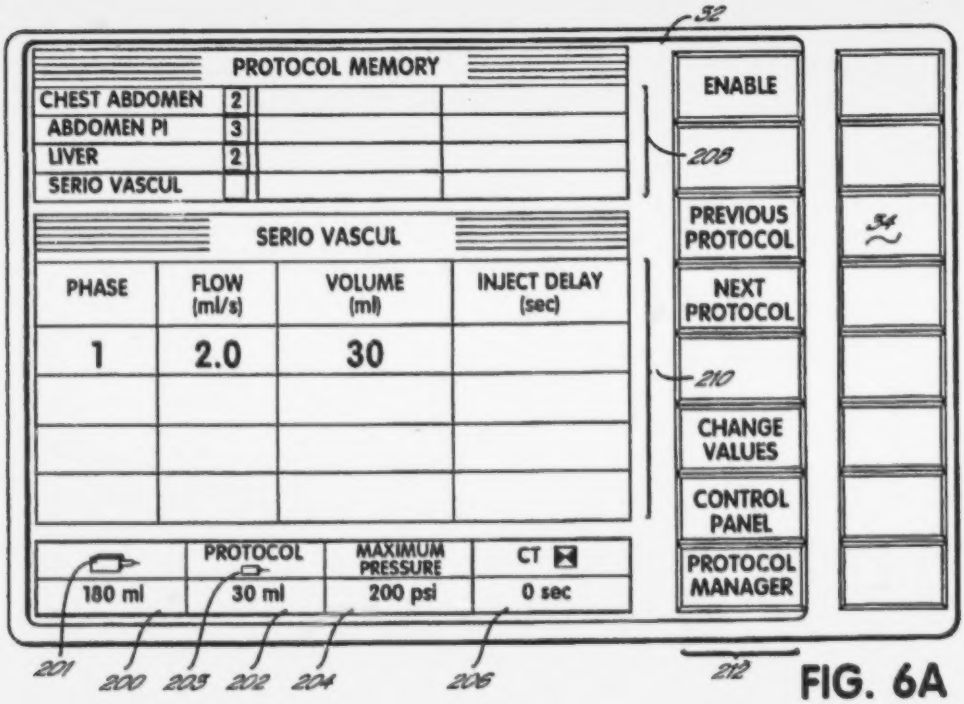

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
ENABLE
208
PREVIOUS PROTOCOL
NEXT PROTOCOL
210
CHANGE VALUES
CONTROL PANEL
PROTOCOL MANAGER
34
201
200
203
202
204
206
212

FIG. 6A

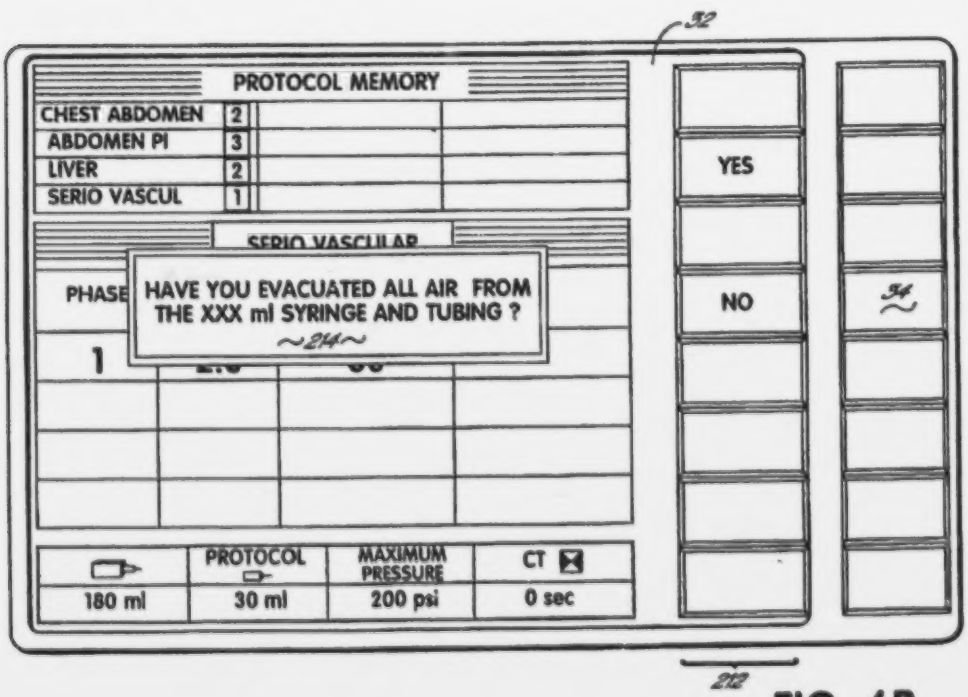

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
HAVE YOU EVACUATED ALL AIR FROM THE XXX ml SYRINGE AND TUBING ?
214
PHASE
1
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
YES
NO
34
212

FIG. 6B

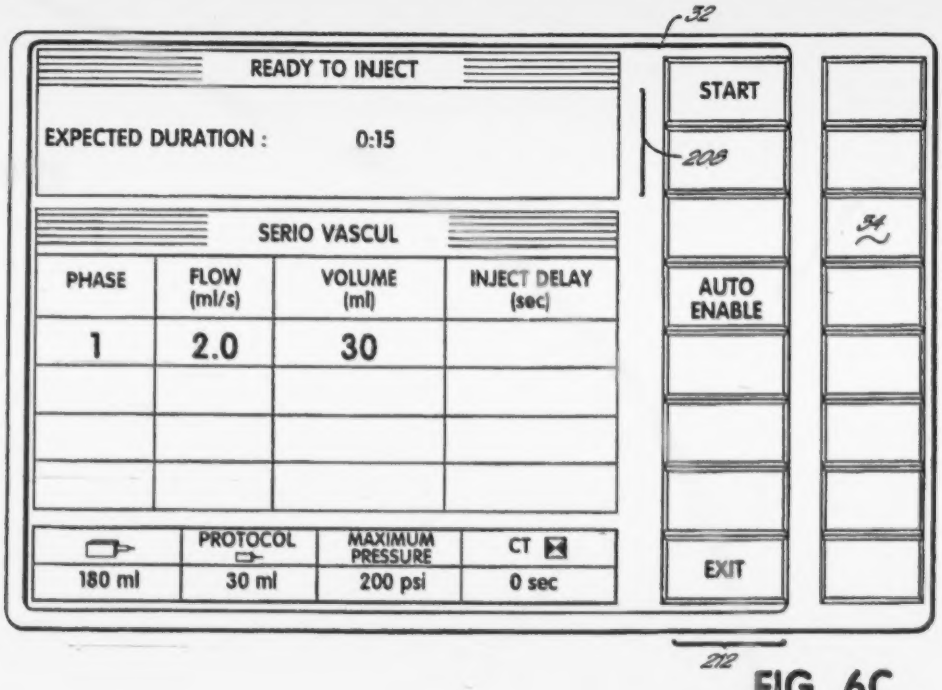

32
READY TO INJECT
EXPECTED DURATION : 0:15
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
START
208
AUTO ENABLE
EXIT
34
212

FIG. 6C

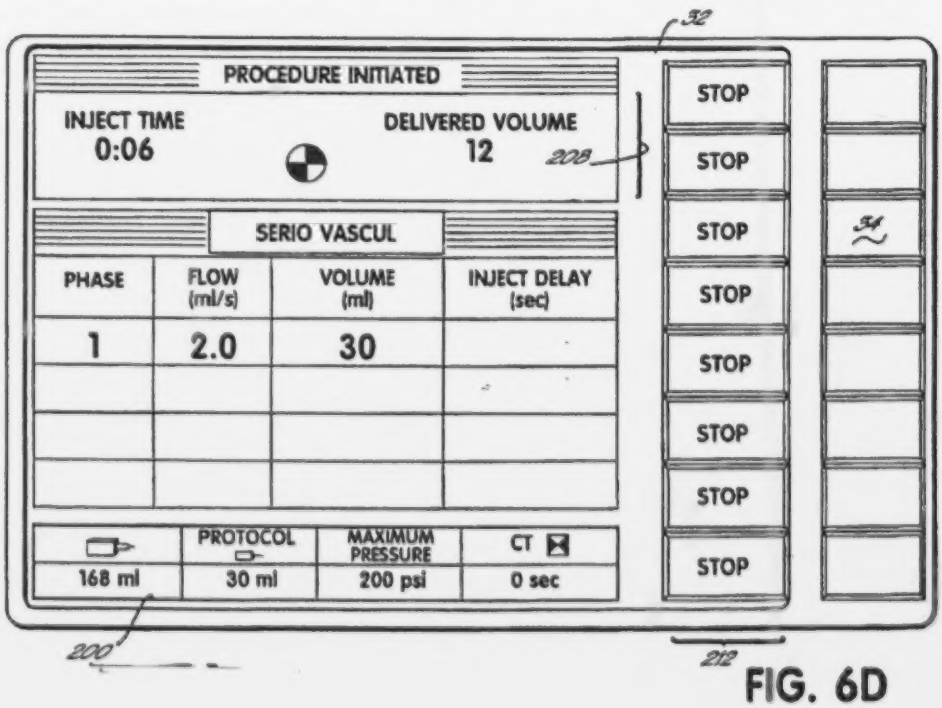

32
PROCEDURE INITIATED
INJECT TIME
0:06
DELIVERED VOLUME
12
208
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
168 ml
30 ml
200 psi
0 sec
STOP
STOP
STOP
STOP
STOP
STOP
STOP
STOP
34
200
212

FIG. 6D

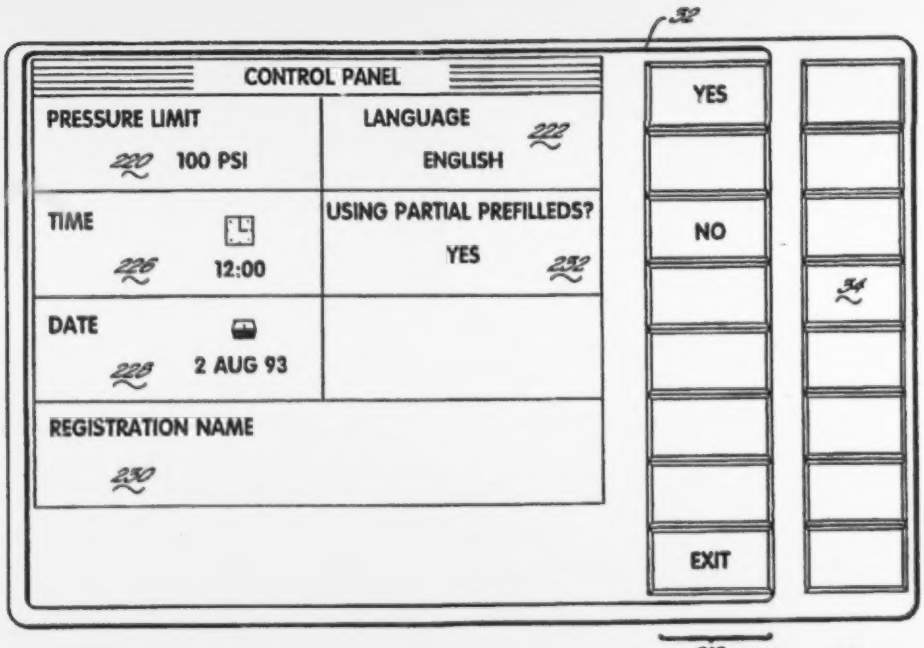

32
CONTROL PANEL
PRESSURE LIMIT
220
100 PSI
LANGUAGE
222
ENGLISH
TIME
226
12:00
USING PARTIAL PREFILLEDS?
YES
232
DATE
228
2 AUG 93
REGISTRATION NAME
230
YES
NO
EXIT
34
212

FIG. 6E

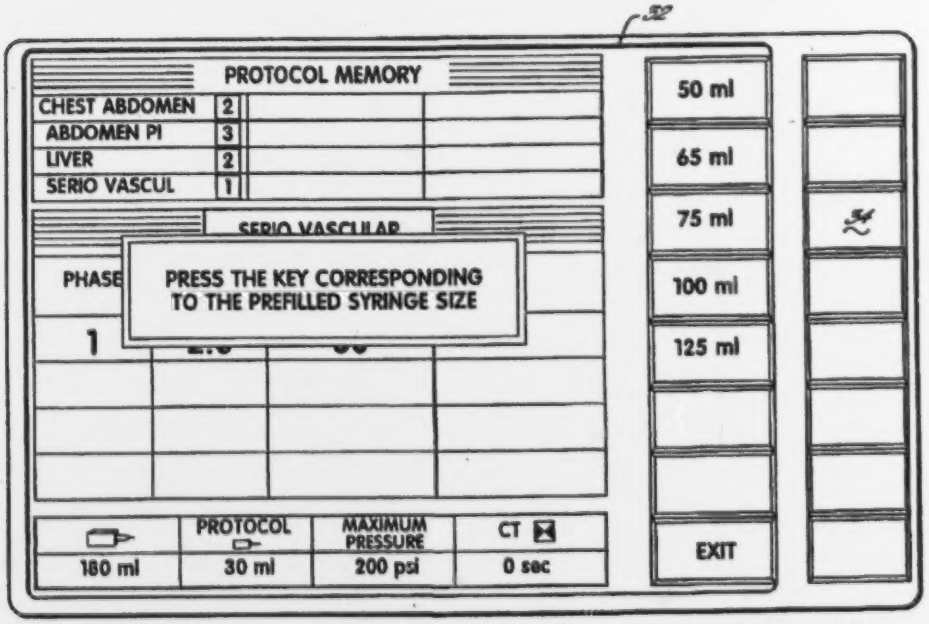

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
SERIO VASCULAR
PHASE
PRESS THE KEY CORRESPONDING TO THE PREFILLED SYRINGE SIZE
1
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
50 ml
65 ml
75 ml
100 ml
125 ml
EXIT
34

FIG. 6F

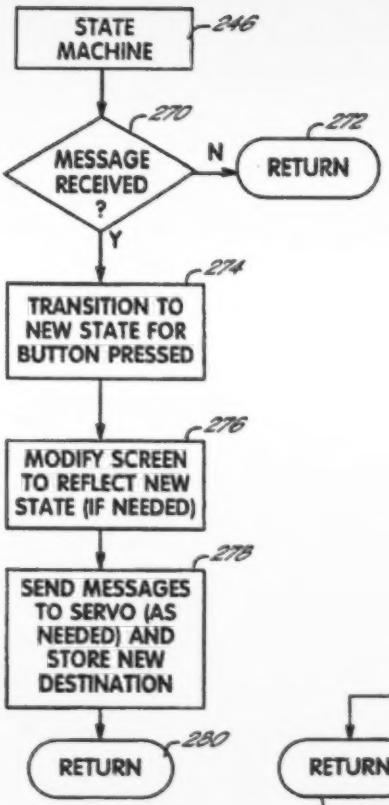

STATE MACHINE
246
270
MESSAGE RECEIVED ?
N
272
RETURN
Y
274
TRANSITION TO NEW STATE FOR BUTTON PRESSED
276
MODIFY SCREEN TO REFLECT NEW STATE (IF NEEDED)
278
SEND MESSAGES TO SERVO (AS NEEDED) AND STORE NEW DESTINATION
RETURN
280

FIG.7B

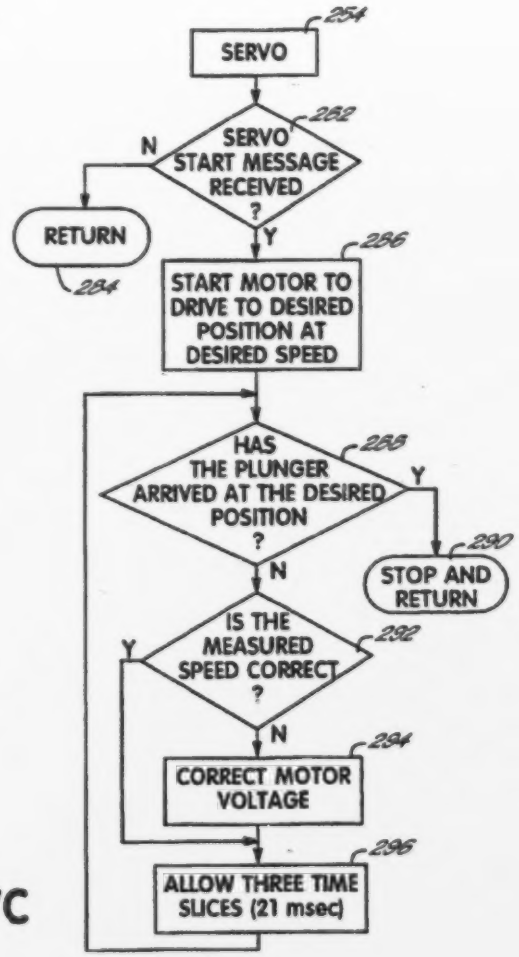

SERVO
254
282
SERVO START MESSAGE RECEIVED ?
N
RETURN
284
Y
286
START MOTOR TO DRIVE TO DESIRED POSITION AT DESIRED SPEED
288
HAS THE PLUNGER ARRIVED AT THE DESIRED POSITION ?
Y
290
STOP AND RETURN
N
292
IS THE MEASURED SPEED CORRECT ?
Y
N
294
CORRECT MOTOR VOLTAGE
296
ALLOW THREE TIME SLICES (21 msec)

FIG.7C

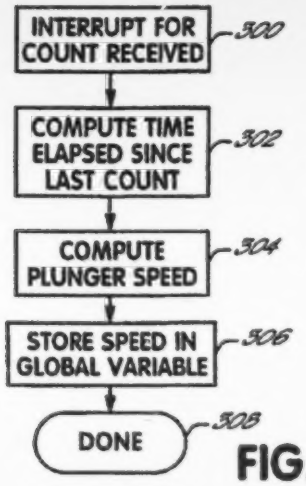

INTERRUPT FOR COUNT RECEIVED
300
COMPUTE TIME ELAPSED SINCE LAST COUNT
302
COMPUTE PLUNGER SPEED
304
STORE SPEED IN GLOBAL VARIABLE
306
DONE
308

FIG.7D

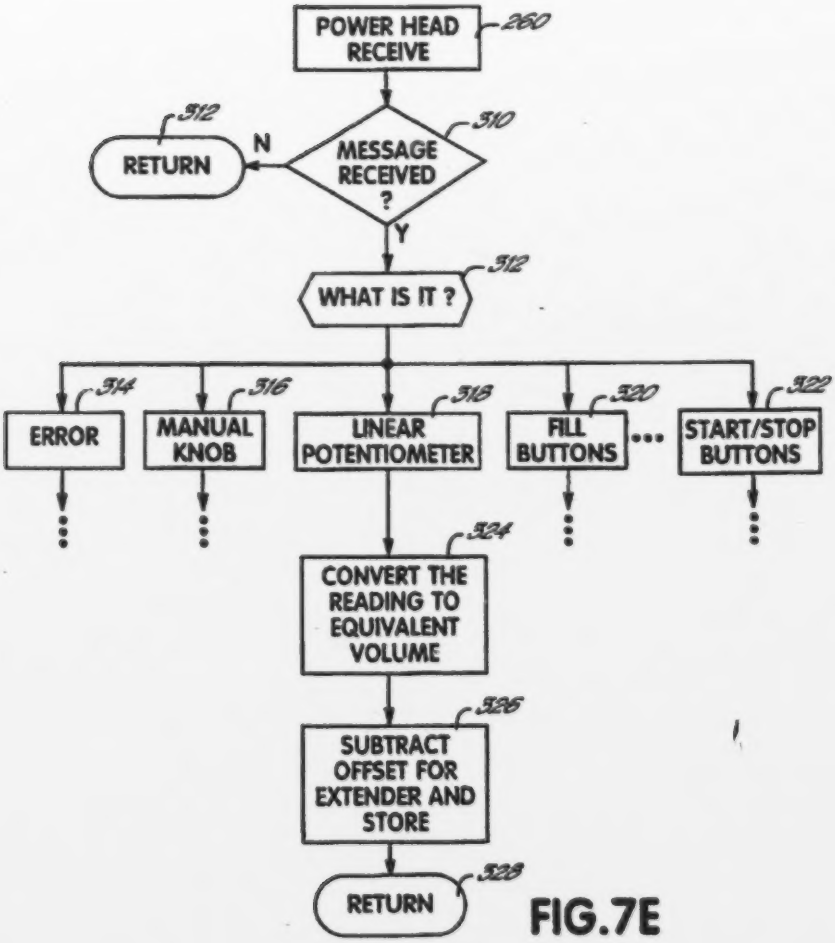

POWER HEAD RECEIVE
260
MESSAGE RECEIVED ?
310
N
RETURN
312
Y
WHAT IS IT ?
312
ERROR
314
MANUAL KNOB
316
LINEAR POTENTIOMETER
318
FILL BUTTONS
320
START/STOP BUTTONS
322
CONVERT THE READING TO EQUIVALENT VOLUME
324
SUBTRACT OFFSET FOR EXTENDER AND STORE
326
RETURN
328

FIG.7E

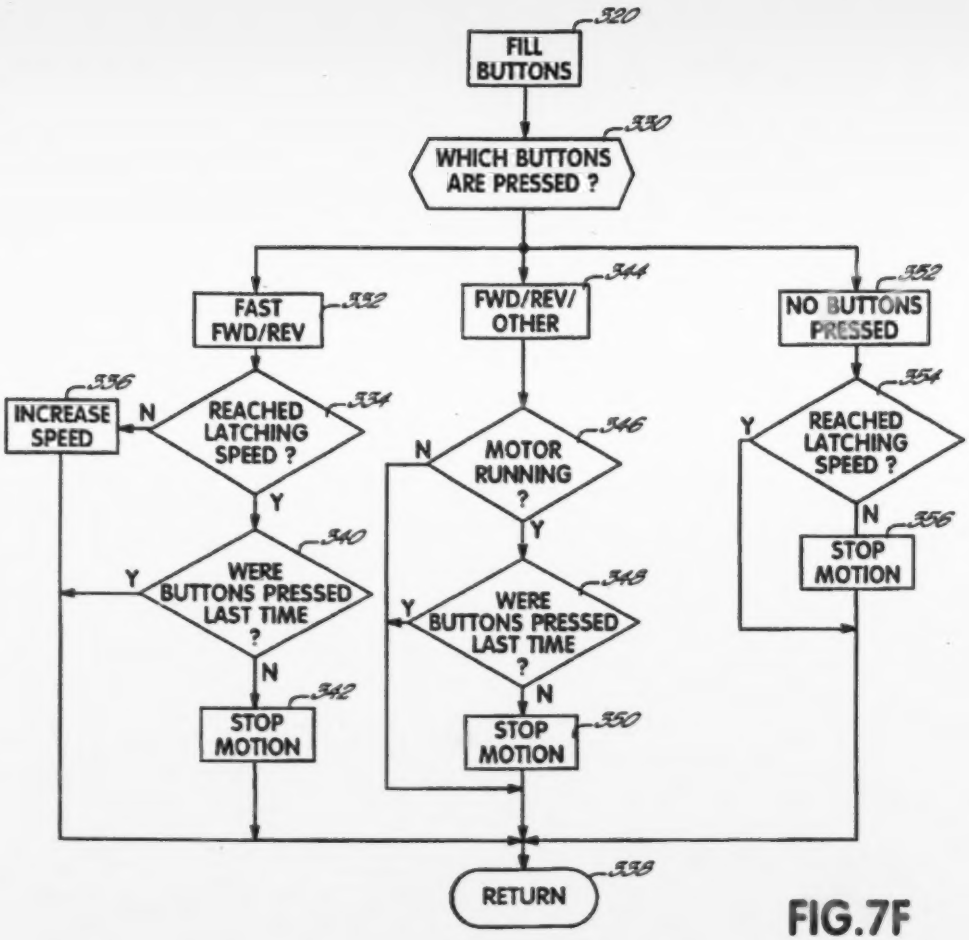

320
FILL BUTTONS
330
WHICH BUTTONS ARE PRESSED ?
FAST FWD/REV
332
FWD/REV/ OTHER
344
NO BUTTONS PRESSED
352
INCREASE SPEED
336
N
REACHED LATCHING SPEED ?
334
Y
346
MOTOR RUNNING ?
N
Y
354
REACHED LATCHING SPEED ?
Y
N
356
STOP MOTION
340
Y
WERE BUTTONS PRESSED LAST TIME ?
N
348
Y
WERE BUTTONS PRESSED LAST TIME ?
N
342
STOP MOTION
350
STOP MOTION
338
RETURN

FIG.7F

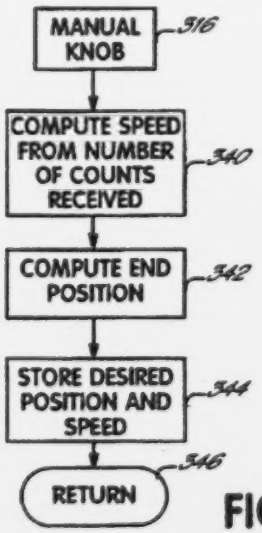

MANUAL KNOB
316
COMPUTE SPEED FROM NUMBER OF COUNTS RECEIVED
340
COMPUTE END POSITION
342
STORE DESIRED POSITION AND SPEED
344
RETURN
346

FIG.7G

CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS

RELATED APPLICATION

This application is a continuation of application Ser. No. 08/157,823 filed Nov. 24, 1993 entitled CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS, now abandoned.

CROSS REFERENCE TO RELATED APPLICATIONS

This application is related to previously-filed U.S. patent application Ser. No. 07/881,782 now U.S. Pat. No. 5,279,569 of Charles S. Neer et al., filed May 11, 1992 for METHOD AND APPARATUS FOR INJECTING FLUID INTO ANIMALS AND DISPOSABLE FRONT LOADABLE SYRINGE THEREFOR, which is assigned to the same entity as this application.

REFERENCE TO MICROFICHE APPENDIX

A microfiche appendix is attached to this application. The software in this appendix is subject to copyright protection. The copyright owner has no objection to reproduction of the appendix in the form that it appears in the U.S. Patent and Trademark Office, but reserves all other rights under copyright law.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as radiopaque media (contrast fluid) used to enhance x-ray or magnetic images, from a syringe, through a tube, and into an animal subject. Injectors are typically provided with an injector unit, adjustably fixed to a stand or support, having a plunger drive that couples to the plunger of the syringe and may move the plunger forward to expel fluid into the tube, or move the plunger rearward to draw fluid into the syringe to fill it.

Injectors often include control circuits for controlling the plunger drive so as to control the rate of injection and amount of fluid injected into the subject. Typically, the control circuit includes one or more manual switches which allow a user to manually actuate the plunger drive to move the plunger into or out of the syringe; typically the user holds down a "forward" or "reverse" drive switch to move the plunger in the indicated direction.

To reduce the risk of infection, in a typical injection procedure the syringe is only used once, and is disposed after use. In some cases, the syringe is inserted into the injector empty. The empty syringe is filled by retraction of the plunger while the interior of the syringe communicates with a supply of the contrast fluid via an injection tube connected between the nozzle of the syringe and the supply of media. Then, bubbles are removed from the syringe, and the injection is performed. At the end of the procedure, the syringe plunger typically is forward, as is the plunger drive.

In some injectors, the syringe can only be removed or replaced while the plunger drive is fully retracted. As illustrated in FIG. 1A, typically an empty syringe **10** is filled with sterile air, with the plunger **12** at the fully retracted position as shown. The plunger drive includes a jaw **18** designed to engage and disengage a button **14** on the rear side of the plunger while the plunger is in this fully-retracted position. Before an empty new syringe can be filled, it is necessary that the plunger be moved fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. Thus, the reloading operation can involve fully retracting the plunger drive to allow removal and replacement of the syringe, then fully advancing the plunger drive and plunger to expel air from the syringe, and then retracting the plunger drive and plunger to fill the syringe. These lengthy, manual movements of the plunger and drive are time consuming.

The above-referenced patent application describes a front-loading injector in which a syringe can be replaced even though the plunger drive is not fully retracted. This injector substantially reduces the number of plunger drive movements necessary to prepare a syringe for a new injection; after an injection, the syringe can be removed and replaced without moving the drive from its fully-advanced position. (The plunger drive jaw **18** can engage and disengage button **14** regardless of the position of the plunger.) After the syringe is replaced, the drive is retracted, filling the syringe for a new injection. Thus, to ready the injector for a new injection, the plunger drive is manually moved once rather than three times.

Another recent development is the use of pre-filled disposable syringes. A pre-filled syringe also reduces the number of manual plunger drive movements necessary to prepare the injector for a new injection. After an injection, the plunger drive is fully retracted, the used syringe is removed and replaced with the pre-filled syringe, and the injector is ready for a new injection. Thus, again, the plunger drive is manually moved once rather than three times.

To prevent infection, contrast media remaining in a syringe after an injection must be discarded. However, contrast media is relatively expensive. For this reason, when preparing for an injection, an empty syringe is filled with only as much media as will be needed for the next injection. For the same reason, pre-filled syringes are sold in a number of capacities, e.g. ranging from 60 to 125 milliliters, allowing the operator preparing for an injection to select a syringe containing only as much media as is needed for the injection.

A typical pre-filled syringe is illustrated in FIG. 1B. In many respects, the pre-filled syringe is identical to the empty syringe shown in FIG. 1A. The barrels **10** and plungers **12** have the same size and profile in both syringes (injectors now in use accommodate only a few FDA approved syringe sizes, e.g., a 200 milliliter size and a 125 milliliter size, so all syringes use these sizes). Furthermore, both syringes have a button **14** which is initially located at the end of the barrel **10** (thus, both syringes are compatible with injectors which are designed to grip a button at the end of the syringe). The main difference is that in the pre-filled syringe of FIG. 1B, the initial location of the plunger **12** is in the middle of the syringe (thus reducing the initial volume of the pre-filled syringe). An extender **16** is attached to button **14** of the plunger, and provides a second button **18** at the end of the syringe which can be gripped by the injector.

SUMMARY OF THE INVENTION

As noted above, at the present state of the art, preparing an injector for an injection requires at least one manual movement of the plunger drive into or out of the syringe barrel, and as many as three such movements. This operation is tedious and inefficient, not only because of the time consumed, but also because the operator must press and hold manual movement switches to produce the movement, and thus is physically tied to the injector and cannot use this time to make other preparations.

In accordance with one embodiment of the present invention, the plunger drive controller has a locked mode in

which motion, initially requested by pressing a manual movement switch, will continue whether or not the operator continues pressing the switch, until the plunger drive reaches its fully-advanced or fully-retracted position. Thus, once the controller has entered the locked mode, the operator may release the manual switch and the desired movement, either advancement or retraction, will continue while the operator makes other preparations for the next injection.

In preferred embodiments, the operator causes the controller to enter the locked mode by pressing the manual movement switch for a predetermined period of time. For safety, the manual movement switch may comprise two buttons which must be simultaneously pressed to produce movement. Movement is initiated by pressing both buttons. While both buttons are held down, the plunger drive controller increases the velocity of movement until the velocity reaches a maximum, at which time the plunger drive controller enters the locked mode. If one button is released before the controller reaches maximum velocity and enters the locked mode, the movement will continue, but at a constant velocity. If the second button is released, the movement will stop. Alternatively, if the controller has reached maximum velocity and entered the locked mode, movement will continue even if both buttons are released; however, if thereafter either button is pressed, movement stops. The controller can provide visual feedback, for example via a light which blinks during motion and lights steadily when the controller is in the locked mode. This light may itself move in synchronism with the plunger drive to provide further feedback on the speed of motion.

As noted, the plunger drive controller is typically manually controlled by means of a switch which, when depressed, causes the plunger drive to move in one of two directions. In accordance with a second aspect of the invention, manual control is improved by providing an adjustment allows the operator to adjust the rate at which the plunger drive moves or accelerates. This permits the operator to customize the operation of the plunger drive controller to enhance individual comfort.

In preferred embodiments, the manual control comprises a wheel which, when rotated, causes the plunger drive to move at a speed which is proportional to the speed of rotation. Alternatively, the manual control may be a forward switch and a reverse switch which cause the plunger drive to move in the indicated direction at a programmable velocity or acceleration.

To operate effectively, the plunger drive controller must determine the location of the plunger **12** relative to the ends of the syringe **10** so that, for example, the controller can determine the amount of contrast media remaining in the syringe. This can be done by a sensor which detects the location of the plunger drive jaw **20**, which is coupled directly to and moves with the plunger **12**. However, a pre-filled syringe may include an extender **16** which changes the relative location of the plunger **12** and the plunger drive jaw **20**, leading to malfunction in the plunger drive controller. In accordance with a third aspect of the invention, malfunction is avoided by storing an offset value representative of the length of the extender **16**, and applying this offset value to the computed drive jaw position.

In preferred embodiments, the offset value may be computed by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value. The controller may be configurable so that this query is not made (for example, if the injector will not be used with pre-filled syringes, and therefore the offset value will not change). Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

These and other aspects will be further illustrated in the following detailed description with reference to the attached drawings, in which:

BRIEF DESCRIPTION OF THE DRAWING

FIGS. **1A** and **1B** are side, partial cut-away views of an empty syringe and a pre-filled syringe, respectively.

FIGS. **2A**, **2B** and **2C** respectively illustrate the console, powerhead, and powerpack of an injector.

FIGS. **3**, **4**, and **5** are electrical and electrical-mechanical block diagrams of the powerpack, console and powerhead, respectively.

FIGS. **6A**, **6B**, **6C**, **6D**, **6E** and **6F** are illustrations of displays produced by the console in operation of the injector.

FIGS. **7A**, **7B**, **7C**, **7D**, **7E**, **7F** and **7G** are flow charts illustrating the software operating within the power pack.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. **2A**, **2B** and **2C**, an injection system according to the invention includes three main components, a console **30**, a powerhead **40** and a powerpack **50**.

The console **30** comprises a liquid crystal display **32** of the type used in notebook computers (e.g., a display sold by Sharp Electronics Corp. of 5700 N.W. Pacific Rim Blvd., Camas, Wash. 98607 as part number LM64P62), coupled to an eight key keypad **34** within a housing **36**. As is further elaborated below, display screens presented on display **32** provide injection information and present the user with menus of one or more possible operations, each operation associated with one of the keys on keypad **34**.

The powerhead **40** includes a mount **42** (such as that described in the above-referenced patent application) which accepts a syringe **10** for an injection. The powerhead includes a plunger drive motor (not shown) for moving plunger **12** forward into and rearward out of syringe **10** during an injection in accordance with a preprogrammed sequence, or protocol, selected by the operator by operation of the console **30**.

The location and movement of the plunger drive is indicated by a light emitting diode (LED) which is mounted to the plunger drive and is visible to the operator through a graduated window **44** in the side of the powerhead **40**. As noted below, this LED flashes when the plunger drive is moving, and lights steadily when the plunger drive has been manually locked into forward or reverse motion in the manner described below.

The side of the powerhead **40** includes six pushbuttons: a start/stop button **45**, a forward manual motion button **46**, a reverse manual motion button **47**, and an enable/accelerate button **48**. The three enable/accelerate buttons **48** perform the same function; there are three buttons instead of one to improve operator accessibility.

The start/stop button **45** is used to start an injection protocol selected at the console, or to stop and restart an injection. During an injection, all of the eight buttons on the keypad **34** of the console **30** will perform an identical start and stop function. Furthermore, a remote handswitch (not shown) may be connected to the powerpack **50** (see below) to perform a start and stop function. (For this reason, the start/stop button **45** includes a picture of a handswitch.)

To manually move the plunger drive, the operator must simultaneously press a motion button **46** or **47** and an enable button **48**. This is a safety feature which reduces the risk of accidental movement of the plunger. If the operator presses the forward button **46** and any of the three enable buttons **48**, the plunger will begin forward motion; conversely, if the operator presses the reverse button **47** and any of the three enable buttons **48**, the plunger will begin reverse motion. Once motion is initiated in either direction, the operator may release one of the buttons; motion will be maintained at a constant velocity in the same direction so long as any one of the five buttons **46**, **47** or **48** is held down. If, instead, after initiating motion in one direction, the operator continues to hold down an enable button **48** and a motion button **46** or **47**, motion will not only be maintained in the same direction, but will be accelerated in this direction until either the operator releases one of the buttons or a maximum velocity is achieved. At any time during the acceleration, the operator may release one of the buttons and hold down the other, and the motion will continue at the same velocity without acceleration. Thereafter, the operator can re-depress the released button, at which time acceleration will begin again.

If the velocity of motion increases to a maximum value, the plunger drive controller (described in more detail below) will enter a locked mode. In this locked mode, movement will continue at the maximum velocity in the same direction even if the operator releases all of the buttons. This frees the operator to perform other tasks when preparing for an injection without being forced to hold manual buttons on the injector until the plunger drive has made the lengthy transition to its fully-advanced or fully-retracted position.

For safety reasons, the locked mode can be terminated readily. If the operator has entered the locked mode and thereafter released all of the buttons, if at any time thereafter any of the buttons is pressed, the plunger drive controller will exit the locked mode and terminate motion.

Two lights **49A** and **49B** mounted on the rear of the powerhead **40** indicate the status of operation of the injector. Light **49A** is an injecting/fault indicator. This light glows while an injection is in process. It will flash if an error is detected. Light **49B** is an enabled indicator. It glows when the injector has been enabled and is ready to perform an injection protocol.

The rear end of the powerhead **40** (opposite mount **42**) includes a jog wheel or switch (not shown in FIG. 2B, see **163**, FIG. 5) used, in the manner described below, to manually activate motion of the plunger drive.

The powerpack **50** illustrated in FIG. 2C contains electronics which communicate with the console **30** and powerhead **40** to perform the functions described above. The powerpack is connected to the console **30** and powerhead **40** by standard computer communications cables (not shown). Signals carried on these cables are interfaced to circuitry inside of the powerhead, console, and powerpack in a manner described below.

As shown in FIG. 3, the circuitry in the powerpack includes a central processing unit (CPU) **52** which controls the operations of the powerhead **40** and console **30**. The CPU is preferably a programmable microprocessor such as the MC68332FN microprocessor, manufactured by Motorola, 2110 East Elliot, Tempe, Ariz. 85284. This microprocessor is a member of the 68000 family of microprocessors and features multitasking support; it is designed for use in so called "embedded" environments such as the circuit described herein, and therefore has more than the usual number direct-wired input-output ports.

The CPU connects to an address bus **54** for addressing a number of memory and communications components and a data bus **56** for retrieving and/or sending data from and to these components. Buffers **55** and **57** aid CPU **52** in interfacing to the address and data busses, respectively. Each of the elements connected to the address and data busses are briefly described below.

An erasable programmable read-only memory (EPROM) **58** connected to data bus **56** contains the program software which operates the CPU **52**. The EPROM contains an operating system, which performs low-level management of the CPU and its communications with other circuits, and a custom program for controlling the console and powerhead to perform injection protocols. In one embodiment, the operating system software is the USX68K operating system, a multi-tasking operating system for 68000 series microprocessors sold by U.S. Software of 14215 N.W. Science Park Drive, Portland, Oreg., 97229, and the custom program is written in the "C" programming language. This custom program is described below, and a copy of the "C" language source code for the custom program appears in the appendix to this application.

A second EPROM **60** connected to data bus **56** contains language information used by the program software in EPROM **56** when generating displays for presentation on the display **32** (FIG. 2A). As will be further elaborated below, the display screens presented on the display **32** include textual descriptions of actions being taken by the injector, and menu selections which the operator can select. The textual portions of these display elements are stored in the language EPROM **56**, from which they are retrieved and inserted into a template as CPU **52** is producing a display screen. Preferably, the language EPROM contains multiple versions of each textual insert, representing different languages, so that the operator can, through menu choices entered at the console keypad **34**, choose a preferred language in which to generate screen displays. An exemplary set of languages suitable for the North American and European markets would be English, German, French and Spanish.

A third, electrically erasable and programmable read only memory (EEPROM) **62** is attached to the data bus. EEPROM **62** stores data in a non-volatile manner (so that it will not be lost when the power is turned off). Among other things, EEPROM **62** stores preprogrammed injection protocols. These protocols are created and stored by the user as desired (details are reviewed with reference to FIG. 6A, below). In addition, EEPROM **62** stores calibration information, used by CPU **52** in interpreting fluid pressure and plunger position information which it receives while performing an injection. Further, EEPROM **62** stores information on the most recently completed injection, such as the injection time and volume, so that this information may be retrieved by the operator. EEPROM **62** also stores operator preference data entered by the operator into the console (see FIG. 6E, below). This includes the preferred display language, time, and date formats. Moreover, EEPROM **62** stores operating parameters such as a programmable pressure limit, and a flag (used in the manner described below) indicating whether the injector will be used with partially pre-filled syringes of the kind illustrated in FIG. 1B. Finally, EEPROM **62** stores the registered name and/or number of the machine owner, to facilitate service and on-line customer support.

Data bus **56** is also connected to a random access memory (RAM) **64** which is used by the operating system to store a stack of register values generated during CPU operations

and machine state information corresponding to currently inactive processes running on the CPU. The application software uses the remaining Space in RAM **64** (as managed and allocated by the operating system) to store variables computed and manipulated during operation of the injector.

Most communications between CPU **52** and the powerhead **40** and console **30** flow through one of two universal asynchronous receiver/transmitters (UARTs) **66**, **68** which are connected to the data bus. A UART is a communications circuit, generally available in integrated circuit form, which collects and buffers incoming and outgoing information to enable asynchronous communications between processors or computing systems over a data link. A suitable UART is the MC68681, sold by Motorola. The first UART **66** is responsible for communications with the powerhead circuitry (see FIG. 5, below), which pass through an interface **70** and a communications cable **71** connected to the powerhead. (However, pulses from the optical encoder **166** on the powerhead (FIG. 5, below) travel directly from interface **70** along line **71** to an interrupt input on the CPU **52**.) UART **66** also handles communications with an auxiliary interface **72**, which can be coupled through a communications cable **73** to a printer to allow CPU **52** to print records of an injection. Alternatively, interface **72** (or another, similar interface) can be used to attach CPU **52** to a remote computer or other external device to allow remote monitoring and/or control of the injector.

The second UART **68** is responsible for communication with the console **30** (FIG. 2A). Two consoles **30** can be connected to the powerpack via cables **75**, **76**.

Cables **75** and **76** carry data representing keystrokes and screen activity between the powerpack **50** and console **30**. This data is encoded in a communications protocol and transmitted in accordance with the RS422 standard. The encoded data is carried via lines **75** and **76** to interface **74** which encodes and decodes transmissions for a second UART **68**. UART **68** routes keystrokes received by either console via interface **74** to CPU **52** via the data bus **56**, and further routes display information produced by CPU **52** to interface **74** for transmission to the consoles via lines **75A** and **76A**.

Cables **75** and **76** also include, on separate conductors, lines **75B** and **76B**, which carry logical signals corresponding to key **38** (FIG. 2A) of each console keyboard. As elaborated below, the software driving the console displays is written so that key **38** is the most frequently used key—depending on the screen being displayed, key **38** will function as an "Exit" key to depart the screen, an "Enter" key to accept a value or selection and depart the screen, or a "Disable" or "Cancel" key to terminate an operation. (Exemplary screens are discussed below with reference to FIGS. 6A–6F.) Because key **38** is the most frequently used key, and because key **38** is used for time-sensitive input such as a cancel command, key **38** is connected to the CPU **52** differently than the other keys. Key **38** is connected directly to the CPU **52** via an interrupt line **79**; when a keystroke is detected, a non-maskable interrupt interface (NMI) **78** (which essentially constitutes a RS422 transmitter and receiver which converts the signal on lines **75B** and **76B** to a clean logic signal on line **79**) sets an interrupt on line **79**, which is immediately detected and subsequently serviced by CPU **52**.

A similar interface is used for the remote handswitch. The cable **81** leading from the handswitch connects to the handswitch interface circuit **80** which among other things, electrically isolates the handswitch from the powerpack ground, and "de-bounces" the handswitch (eliminates electrical noise created when the switch is pressed or released) so as to provide a clean logic signal indicating whether the handswitch button is being pressed or is released. This logic signal is connected, via line **82**, to a time processor unit (TPU) port on CPU **52**. CPU **52** reads the logic signal at this TPU port and responds appropriately according to the software in EPROM **58**.

The last component on the CPU data bus **56** is an analog to digital converter (A/D) **84**. This converter is used to generate a digital signal, readable through data bus **56**, which corresponds to an analog signal received on line **85**. A suitable A/D converter is the LT1094, sold by Linear Technology of 1630 McCarthy Blvd., Milpitas, Calif. 95035. A/D converter **84** is used by the motor servo control circuitry described below. The CPU has two additional interfaces to the motor servo control circuitry: an interface on line **87** to a digital to analog converter (D/A) **86** (which generates an analog signal on line **88** corresponding to a digital signal received on line **87**, for example the AD7245, sold by Analog Devices of One Technology Way, P.O. Box 9106, Norwood, Mass. 02062), and a second interface on line **90** to pressure limit control circuit **92**. These interfaces (lines **87** and **90**) connect to synchronous peripheral interface (SPI) channels on the microprocessor, and are controlled in accordance with the software in EPROM **58**.

The D/A **86**, A/D **84**, servo control **94**, pressure limit control **92**, and pressure sense **96** circuits collectively form a motor servo control circuit which controls the operation of the motor **98** which drives the syringe plunger into and out of the syringe. (Motor **98** is shown for clarity, but it should be understood that motor **98** is physically located in the powerhead **40** (FIG. 2B, 5); lines **91** and **93** connect to the motor through several conductors of the computer interface cable connecting the powerhead **40** and the powerpack.)

Servo control circuit **94** responds to an analog voltage produced by D/A **86** on line **88** and produces a corresponding voltage between lines **99** and **100**. The voltage on lines **99** and **100** is transformed by transformer **102** to a level sufficient to drive motor **98** via lines **91** and **93**. Servo control circuit **94** contains a flyback transformer circuit which produces an output voltage related to the duty cycle of a switching FET. This duty cycle is produced by a UC3525 pulse width modulation (PWM) circuit—an integrated circuit which produces a 100 kHz digital output signal having a duty cycle which varies from 0% to 50% in response to an analog input voltage on line **88**. A suitable PWM circuit is the UC3525, sold by Unitrode of 7 Continental Boulevard, Merrimack, N.H. 03054. Thus, CPU **52** controls the speed and power output of motor **98** by writing a digital word representing a desired output voltage to D/A **86** via lines **87**; this digital word is then converted to an analog signal, and the analog signal is converted to a pulse width modulated control signal in the servo control, resulting in the desired output voltage at the motor.

Pressure sense circuit **96** includes a current sense circuit of which detects the current flow through line **93** (i.e., through the motor) and produces analog signals on lines **104** and **85** proportional to the detected current. In essence, this current sense circuit comprises a low-value, high power rating resistor in series with line **93** which attached to the motor **98**. A differential voltage amplifier (based on a low-noise, high common mode rejection op-amp) senses the voltage across the resistor and converts it to an analog voltage on lines **85** and **104**. The current flow through the motor is proportional to the force exerted by the motor and therefore to the injection pressure. Thus, the analog signals

produced by pressure sense circuit **96** can be used to derive the injection pressure.

Pressure limit control circuit **92** uses the analog signal on line **104** to perform a hardware pressure control function. Pressure limit control circuit **92** contains a commercially available digital potentiometer, used to produce an analog comparison voltage. A suitable potentiometer is the DS1267, sold by Dallas Semiconductor of 4350 Beltwood Parkway South, Dallas, Tex. 75244. CPU **52** (via lines **90**) programs this potentiometer to produce a comparison voltage corresponding to the maximum allowable pressure. Pressure limit control circuit **92** includes a comparator which compares the analog signal on line **104** produced by pressure sense circuit **96** to the comparison voltage. If the pressure exceeds the maximum allowable pressure (indicating a failure in the CPU **52**), a digital signal is transmitted on line **105** to servo control circuit **94**, which in response ignores the analog signal on line **88**, and instead reduces the voltage on lines **99** and **100** to halt the motor. Thus, once the CPU **52** has programmed pressure limit control circuit **92** with the correct maximum pressure, the injector will not exceed this pressure even if the CPU **52** fails.

Under normal conditions, this hardware pressure limit will not be activated, because CPU **52** continuously obtains feedback on the performance of the motor and the pressure produced and controls the motor through D/A **86** to achieve the desired injection protocol. CPU **52** obtains feedback on an ongoing injection from three sources: (1) feedback on the injection pressure is obtained from A/D **84**, which produces a digital word on bus **56** corresponding to the analog voltage on line **85** produced by pressure sense circuit **96**; (2) feedback on the motor speed is obtained from an optical encoder **166** physically coupled to the motor inside of the powerhead **40** (elaborated with reference to FIG. **5**, below); and (3) feedback on the position of the plunger inside of the syringe is obtained from a linear potentiometer **168** physically coupled to the plunger (see FIG. **5**, below). Using this information, CPU **52** carefully controls the injection pressure, volume and speed according to a pre-programmed protocol under control of software in EPROM **58**.

Power for the powerpack, powerhead, and console display is supplied by the AC power lines **107** and **108**. The AC line voltage is conditioned by a conventional power supply circuit **106** which includes a transformer which can be adjusted for use with non-United States line voltages, and a voltage sense circuit for selecting the appropriate transformer based on the detected line voltage. The power may be turned off by unplugging the injector, or preferably by a toggle switch which opens and closes a solid-state relay in remote on/off circuit **110**.

Referring to FIG. **4**, the console circuitry is also built around a general purpose CPU **120**. A suitable microprocessor is the MC68332FN. The address bus **122** and data bus **124** connected to CPU **120** connect to a number of supporting circuits. Program ROM **126** contains the software which directs CPU **120**. (This software is written in assembly language, and is included in the attached appendix). Font ROM **128** includes font information retrieved by CPU **120** in producing fonts for text generated on the display screen. These fonts include foreign-language characters where necessary to support foreign language text. RAM **130** is used by microprocessor in performing display and retrieval operations. Battery-backed RAM **132** stores the current time of day, so that the powerpack may make a date and time-stamped record of an injection.

The primary function of the console circuitry is to generate screens on the display **32**, and to receive keystrokes from the eight-key keypad **34** (FIG. **2A**) and relay the keystrokes to the powerpack. Displays are generated by a display controller **134**, such as the F82C455 VGA controller sold by Chips & Technologies of 3050 Zanker Road, San Jose, Calif. 95134. This VGA controller interacts with CPU **120** via an address buffer **136** and data buffer **138**, and stores screen information in a dynamic random access memory (DRAM) **140**. Information is sent over lines **142** to the display **32**.

Keystrokes from the keypad are received by keyboard interface circuit **144** which "debounces" the keystrokes, producing clean logic signals on lines **146**. These logic signals are fed back to CPU **120** so that it may confirm keystrokes by producing an audible tone through speaker control circuit **150**. Speaker control circuit also generates unique audible signals to indicate other operations, such as the initiation of an injection, or to notify the operator that scanning should begin. A suitable controller is the MC3487, sold by Motorola.

CPU **120** communicates with the powerpack via an RS422 interface circuit **148** which sends and receives digital signals over lines **75** and **76**. Interface circuit **148** also receives and forwards keystrokes directly from keyboard interface **144**. The eight keys on the console form a single, eight bit byte of information (where each bit indicates whether the key is pressed or released). This byte is coupled directly to CPU **120** via a "245" type logical buffer.

+28 Volt DC power is received from the power supplies in the powerpack via lines **152**. A power supply circuit **154** regulates this +28 Volt DC power line into a collection of supply voltages, as needed by the various circuitry in the console. Furthermore, a power inverter circuit converts +12 Volt DC power produced by the power supply circuit **154** into low-current 600 Volt AC power supplies for energizing the liquid crystal display.

Referring to FIG. **5**, the powerhead also includes a circuit board **160** including microprocessor to perform communications with the powerpack **50** (FIG. **2C**). A suitable microprocessor is the 68HC11E2, sold by Motorola, which is a low-cost, minimal functionality microprocessor in the 68000 family. The circuit board receives and forwards keystrokes from the buttons on the keyboard **162** (described above), and electrical pulses indicating movements from the manual knob **163** mounted on the rear of the powerhead. A suitable manual knob is the model 600 thumbwheel, sold by Clarostat of 1 Washington Street, Dover, N.H. 03820. The circuit board also lights and extinguishes the injecting/fault indicator light **49A** and the enabled indicator light **49B**.

The motor **98** is coupled to a gear box which translates rotary motion of the motor to linear translation of the plunger. One suitable motor is the CYMS A2774-2 motor, sold by Barber-Colman, P.O. Box 7040, Rockford, Ill. 61125. The rotation of the motor is detected by optical encoder **166** (encoder **166** essentially comprises a pinwheel which rotates between a light source and a light detector to produce electrical pulses, for example the HEDS-9100 encoder, sold by Hewlett-Packard of 3003 Scott Boulevard, Santa Clara, Calif. 95054). Encoder **166** sends electrical pulses to circuit board **160**, which relays them to powerpack **50**, allowing CPU **52** on the powerpack to monitor movement of the motor.

The position of the plunger is detected by a linear potentiometer **168**, for example the LCPL200, sold by ETI Systems of 215 Via Del Norte, Oceanside, Calif. 92054. The wiper **169** of potentiometer **168** is mechanically coupled to and moves with the plunger **12**. A DC voltage drop is placed

across the potentiometer terminals **170** and **171**, and as a result, an analog voltage representative of the location of the plunger and wiper **169** is produced at the wiper **169**. An A/D converter on circuit board **160** converts this analog voltage to a digital signal which circuit board **160** forwards to the powerpack **50**.

Circuit board **160** also detects the output of two Hall effect sensors **172** and **174**. The powerhead has a removable face plate **42** (FIG. 2B). There are currently two different face plates having differently-sized apertures for accepting differently-sized syringes. Thus, although the face plate need not be removed to replace the syringe, it may be removed to use a different syringe size. Sensor **172** detects whether face plate **42** is open, and if so circuit board **160** sends a message to powerpack **50** which prevents any further injection procedures until the face plate is closed. Sensor **174** detects the size of the face plate in use. Currently, only one of the two face plates includes a magnet which triggers sensor **174**; thus, circuit board can determine which face plate has been installed by determining whether sensor **174** has been triggered. This information is also forwarded to CPU **52** in the powerpack so that CPU **52** may compensate for the different syringe sizes when controlling motor **98** (as described below).

At the direction of CPU **52**, circuit board **160** also controls heater blanket **176**, which heats the contrast fluid in the syringe. Furthermore, circuit board **160** controls movement indicator board **178**. Movement indicator board **178** is mechanically coupled to the plunger **12** and includes two light emitting diodes LEDs **179** which are visible through window **44** on the powerhead (FIG. 2B). LEDs **179** provide the operator with feedback on the position of the plunger, by correlating the position of the diodes with the graduated scale on window **41**. The two sides of the window **41** contain different graduated scales: one calibrated for large syringes and one for small syringes. Depending on the syringe size detected by sensor **174**, the LED next to the appropriate graduated scale is illuminated. Furthermore, as discussed in more detail below, when the plunger is moving, CPU **52** directs circuit board **160** to flash the LED. Also, when the CPU **52** enters its "locked mode" (discussed above), CPU **52** directs circuit board **160** to steadily light the LED. Thus, LEDs **179** provide operator feedback on the plunger position, direction of motion, and the "locked mode".

Referring to FIGS. 6A–6F, an injection protocol will be described from the operator's perspective. The main operating screen is illustrated in FIG. 6A. Box **200**, which is associated with an iconic representation **201** of the powerhead, identifies the current volume of contrast media in the syringe. Box **202**, which is associated with an iconic representation **203** of the syringe, identifies the total volume which has been dispensed during the currently selected protocol. Box **204** identifies the pressure limit pre-selected by the operator for the procedure, and box **206** identifies a scan delay (in seconds), which is the delay from the time the operator initiates an injection (either with the handswitch, a key on the console or a button on the powerhead) until the x ray or magnetic scan of the subject should begin (at the end of this delay. CPU **120** produces a tone indicating to the operator that scanning should begin; alternatively, scanning could be automatically initiated by a suitable electrical connection between the scanner and injector). In the illustrated situation, the syringe contains 180 ml of fluid, 30 ml of which will be used by the currently selected protocol, the pressure limit is 200 psi and there is no scan delay.

In the display illustrated in FIG. 6A, the upper regions of the screen display stored injection protocols. Region **208** identifies protocols which the operator may select, and region **210** gives details of the currently selected protocol. As shown in region **210**, a protocol comprises a number of phases; during each phase the injector produces a pre-programmed flow rate to output a pre-programmed total fluid volume. The illustrated protocol "SERIO VASCUL" has only one phase; however, other protocols which can be selected by the operator have multiple phases. In region **208**, protocols are identified by name and by number of phases; thus, as illustrated, the "LIVER" protocol has 2 phases and the "ABDOMEN PI" protocol has 3 phases.

The user can select protocols, enable an injection, and otherwise navigate through display screens by pressing the buttons on the keypad **34** next to the display. Region **212** of the display is dedicated to identifying the functions available from the buttons on the keypad **34**. Thus, in this display illustrated in FIG. 6A, the user may select the previous or next protocol in the list in region **208** by pressing the buttons next to the words "PREVIOUS PROTOCOL" and "NEXT PROTOCOL", respectively, on the display. The user may also change and store the flow, volume and inject delay values for the current protocol by pressing the button next to "CHANGE VALUES"; doing so will alter the function of the keypad and region **212** of the display, so that the operator may select a value, increment and decrement the value, select characters to form or edit a protocol name, and then return to the display shown in FIG. 6A. From FIG. 6A, the operator may also enter a control panel display (see FIG. 6E, below) to adjust operating parameters and other data. Also, the operator may enter a protocol manager in which the operator may rename or delete protocols, and may determine the order of the protocol list shown in region **208**. Finally, the user may also enable an injection from the display illustrated in FIG. 6A by pressing the button next to "ENABLE".

As shown in FIG. 6B, when the user enables an injection, as a safety measure, the injector first presents a text box **214** which asks the operator whether all of the air has been evacuated from the syringe. Region **212** of the display contains only the words "YES" and "NO", indicating that the operator must answer the question as either yes or no. If the button next to "NO" is pressed, the injection will be cancelled. If the answer is "YES", the injector will proceed to an enabled state, illustrated in FIG. 6C. Here, region **208** of the display indicates the expected duration, and region **212** includes the word "START", "AUTO ENABLE" and "EXIT". If the operator presses the button next to "EXIT", the injector will return to the state illustrated by FIG. 6A. If the operator presses the button next to "AUTO ENABLE", the injector will toggle into and out of the auto-enabled mode, as confirmed by a briefly-displayed box in the center of the screen. If the operator presses the button next to "START" the injection will begin and the injector will move to the state illustrated by FIG. 6D.

While an injection is proceeding, the display shown in FIG. 6D is displayed. In this display, region **208** indicates the total injection time and the volume (in ml) delivered to the patient. Region **212** shows the word "STOP" next to each of the buttons on the keypad **34**, indicating that the operator may stop the injection by pressing any of the buttons (or by pressing the start/stop button **45** on the powerhead, or by pressing the handswitch). In addition, in box **200**, the total volume of fluid in the syringe counts down as fluid in injected into the subject.

After the injection protocol has completed, the injector will return either to the state illustrated by FIG. 6A or to the state illustrated by FIG. 6C. If the operator put the injector

in the auto-enable mode by pressing "AUTO ENABLE" at FIG. 6C, the injector will return to the state illustrated by FIG. 6C. However, if the operator did not put the injector into the auto-enable mode, the injector will return to the state illustrated by FIG. 6A. Thus, by placing the injector in auto-enable mode, the operator can more easily repeat an injection protocol; this can be useful where, for example, the contrast media dissipates relatively rapidly, and multiple images will be taken on the same area of the subject. By using "AUTO ENABLE", the operator may replenish the contrast media just before each image by pressing a single key (or the handswitch), without re-enabling the injector.

As noted above, injection operators may wish to use prefilled syringes for injections. However, prefilled syringes often include extenders which reduce the filled volume of the syringe (syringes of this type are known as "partial pre-filled" syringes). The injector described herein includes a feature for compensating for the reduced volume of partial pre-filled syringes, described below.

As noted above, to set up the injector, the operator may enter the "Control Panel", illustrated in FIG. 6E. In the control panel, the display identifies the current operational settings of the injector. Thus, the control panel includes a box **220** which identifies the current pressure limit, a box **222** which identifies the current language (as noted above, the operator may choose a language for the textual portions of the display), boxes **226** and **228** which identify the current time and date, and a box **230** which identifies the owners registration name and/or number. This information is entered using the keypad and region **212** of the display in the manner discussed above.

An additional box **232** on the "Control Panel" display is used to indicate whether partial pre-filled syringes will be used with the injector. Box **232** will include the word "YES" or "NO", as selected by the operator (as shown in FIG. 6E, when the user attempts to modify this box, region **212** of the display provides a menu with the choices "YES" or "NO").

If the operator has modified box **232** to indicate that partial pre-filled may be used (i.e., box **232** has a "YES"), then the enable procedure described above is modified slightly. If partial pre-filleds may be used, after the operator enables an injection by pressing "ENABLE" at the display of FIG. 6A, the injector presents the screen illustrated in FIG. 6F, in which the operator must identify the pre-filled syringe size by pressing a button next to "50 ml", "65 ml", "75 ml", "100 ml", or "125 ml". Once the operator has identified the pre-filled syringe size, the injector will continue to the display illustrated in FIG. 6B. CPU **52** (FIG. 3) will then compensate for the extender in the syringe, in the manner described below with reference to FIG. 7B.

Referring to FIG. 7A, the program operating in CPU **52** is initiated **240** when the power is turned on. The program first initializes **242** the hardware and software attached in powerpack **50**, powerhead **40** and display **30**. Then, CPU **52** performs **244** diagnostics to ensure that the injector is operating properly; essentially, this involves sending test data to various hardware elements and verifying that the appropriate responses are received.

After these diagnostics have passed, CPU **52** initiates a number of "threads", or parallel processes; thereafter, these processes are time-multiplexed on CPU **52** under control of the above-described USX68K operating system. These threads communicate with the operating system and with each other by "messages" or semaphores—essentially, inter-process communications are placed in a globally accessible area, managed by the operating system, where they can be later retrieved by other threads. The operating system allocates processing time to the threads. Much of the time, a thread will be "inactive", i.e., it will not have any pending operations to perform. The threads are generally written so that, if the thread is inactive, it will notify the operating system of this fact ("return time" to the operating system) so that the operating system can reallocate processing time to another thread.

The operating system allocates processing time to threads in a prioritized, round-robin fashion. Thus, the operating system will provide processing time to each thread generally in turn; if an active, low-priority thread uses more than a maximum amount of processing time, the operating system will interrupt the thread, and provide other, higher priority threads with an opportunity to use processing time. However, a high-priority thread will not be interrupted by lower priority threads, regardless of whether the high-priority thread uses more than the maximum amount of processing time. Under normal operation, most of the threads are inactive, and there is no conflict between threads for processing time; however, in those occasions where there is a conflict, this prioritized system allows the most important threads to continue uninterrupted where necessary. It should be noted, however, that even the highest priority thread (servo thread **254**) occasionally returns time to the operating system (at those moments where an interruption can be tolerated), so that other threads are able to continue their operations even while the highest priority thread is active.

The threads operating in the CPU **52** generally fall into two categories: "communicating" threads which send information into and out of the powerpack **50**, and "operating" threads which generate or process the information sent or received by the powerpack. There are two operating threads: state machine thread **246** and servo thread **254**.

State machine thread **246** directs the console **30** to produce screen displays of the type shown in FIGS. 6A–6E, and also processes button presses by the user. Thread **246** is essentially a state machine, where each "state" corresponds to a display screen, and each operator keystroke produces a state transition. The software in program EPROM **58** (FIG. 3) essentially defines a state transition diagram, identifying specific states, displays associated with those states, and, for each state, the keystrokes or other activity which will cause a transition to another state.

As shown in FIG. 7B, when initiated, thread **246** looks **270** for a message, for example a message from a communications thread indicating that console button was pressed, or a message from the servo thread indicating that the display should be updated to reflect recent injection activity. If no message has been received, the thread returns **272** time to the operating system. However, if a message has been received, the thread uses the software in program EPROM **58** to identify and transition **274** to the new state associated with the received keystroke or activity. In some cases, e.g. where the operator has pressed an invalid button, the new state will be the same as the old state; in other cases, the new state will be a different state. If the new state is a different state, the state machine thread sends messages to the appropriate communication thread to modify **276** the screen to reflect the new state. In addition, the state machine thread may send **278** messages to the servo thread, e.g. to notify the servo thread that the operator has pressed a button which starts a protocol. When this is completed, the state machine returns **280** to the operating system.

When a start message is sent to the servo thread, the thread sending the message initiates one or more global

variables to indicate the kind of movement requested. Eight global variables (variables managed by the operating system and accessible by all threads), organized into four pairs, are used for this purpose. Each pair of variables identifies a desired new position for the plunger and a speed at which the plunger should move to that position. Four protocol phases can be described by the four variable pairs, and thus may be executed in one message to the servo thread. Thus, when the state machine thread sends **278** a message to the servo thread, it computes one or more desired ending positions and speeds from the selected protocol, and places the computed values into global variables.

Referring to FIG. 7C, when initiated by the operating system, the servo thread **254** first checks **282** for a message telling the servo to start motion of the plunger. If no message is received, the servo thread returns **284** time to the operating system. If, however, a start message has been received, the servo thread starts **286** the motor to move to the desired position indicated by a global variable at the desired speed indicated by a global variable. At this point, the servo thread enters a loop; during each iteration the loop checks **288** if the plunger has arrived at the desired position (the plunger position is determined by the powerhead receive thread **260** as illustrated in FIG. 7E, below), and if so, the loop terminates and the servo thread stops **290** the motor and returns. However, if the plunger has not arrived at the desired position, the servo thread checks **292** if the speed of the motor is correct (the motor speed is measured by an interrupt routine illustrated in FIG. 7D, below). If the motor speed is incorrect, it is corrected **294** by adjusting the motor voltage. Once these steps are completed, the servo thread allows **296** the operating system three time slices (about 21 milliseconds) to operate other processes, after which it returns to step **288** to close the loop.

Referring to FIG. 7D, as noted above, the motor speed is measured by an interrupt routine. When a pulse is detected from the optical encoder **166** (FIG. 5) attached to the motor **98**, the processor in the powerhead circuit board **160** causes an interrupt to travel on line **71** to CPU. **52**. When this interrupt is received **300**, the interrupt routine computes **302** the time elapsed from the previous count interrupt, and from this elapsed time computes **304** the plunger speed. This speed value is stored **306** in a global variable (where it can be accessed by the servo routine), and the interrupt is done **308**.

Referring to FIG. 7E, the powerhead receive thread **260** is responsible for receiving messages from the powerhead and performing a number of tasks in response, including relaying manual movements of the plunger to the servo thread and (as noted above) relaying position measurements to the servo thread during movement of the plunger.

When the operating system initiates **260** the powerhead thread, the thread first checks **310** for any messages; if none have been received, the thread returns **312** time to the operating system. However, if the thread has received a message, it determines **312** what the message is and acts appropriately (this determination is illustrated for clarity as a multi-way branch, but in the code in the fiche appendix it is implemented as a series of individual tests performed on in sequence). The message may contain an error message **314**, a manual knob movement **316**, a linear potentiometer reading **318** (which are periodically generated by the powerhead), a fill button reading **320** (which is periodically generated by the powerhead), a start/stop button press **322**, or several others (multiple messages may be received at one time).

As shown in FIG. 7E, if the message contains a linear potentiometer reading **318**, the reading is converted **324** into an equivalent volume (using calibration readings stored in EEPROM **62**). Then, an offset value (which compensates for the presence of the extender in a partial pre-filled syringe), is subtracted **326** from the computed volume, and the result is stored in a global variable, where it can be later accessed by the servo thread at step **288** (FIG. 7C). The offset value used in step **326** is generated when the user identifies the partial pre-filled size in response to the display shown in FIG. 6F; if partial pre-filled syringes are not used, the offset is set to a constant zero value. Once the adjusted volume is stored, the powerhead thread returns **328** time to the operating system.

As shown in FIG. 7F, when a fill button reading is received (i.e., the received message indicates the state of buttons **46**, **47** and **48** on the keyboard **162** of the powerhead), the powerhead thread first determines **330** which button, or buttons, are pressed.

If a "fast" button **48** and the forward button **46** or reverse button **47** are pressed **332**, the thread first determines **334** whether the motor is at its maximum, latching speed (by reading the global variable indicating the motor speed, as produced by the interrupt routine illustrated in FIG. 7D). If not, the thread increases **336** the motor speed in the indicated direction—by increasing the value of the global variable identifying the desired speed, setting the global variable identifying the desired location to identify the end of the syringe (and sending a start servo message to the servo thread if the motor is not already running)—and returns **338** time to the operating system. If, however, the motor has reached its latching speed, then the thread determines **340** if buttons were pressed the last time a fill button reading was processed. If so, then the operator has accelerated the motor to its maximum speed and is continuing to hold down the buttons. In this situation, the motor should continue running at its maximum speed; therefore, the thread simply returns **338** time to the operating system. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If the operator is pressing **344** the forward or reverse buttons alone, or any other combination of buttons, the thread first determines **346** if the motor is running (by checking the value of the global variable indicating the motor speed). If the motor not running, then a single keystroke will not start it running, so the thread simply returns **338** to the operating system. If, however, the motor is running, then the thread determines **348** if buttons were pressed the last time a fill button reading was processed. If buttons were pressed last time, then the operator is merely trying to keep the motor running at its current speed by holding a button down; therefore, in this situation, the thread simply returns **338** to the operating system, allowing the motor to continue running. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If no buttons are pressed **352**, the thread simply determines **354** if the motor is at its latching speed. If not, the thread stops **356** the motor and returns time to the operating system. Otherwise, the thread returns **338** directly, allowing the motor to continue running at the latching speed.

Referring to FIG. 7G, manual motion can also be created by turning the manual knob **163** (FIG. 5) mounted on the rear of the powerhead. As noted above, the powerhead CPU **160** regularly reports movements of the manual knob to the powerpack CPU **52**. This report identifies the direction of rotation and the number of electrical pulses received from the knob since the last report (more pulses indicating greater speed of rotation). When a manual knob message is received **316**, the powerhead receive thread first computes **340** a desired plunger speed from the number of pulses identified in the message, and computes **342** a desired end position from the number of pulses and the direction of rotation of the knob. These are then stored **344** in global variables accessible to the servo thread as described above. If the motor is not already running, the powerhead receive thread also sends a servo start message to the servo thread. Then the thread returns **346** time to the operating system.

The invention has been described with reference to a specific embodiment. However, it will now be understood that various modifications and alterations can be made to this specific embodiment without departing from the inventive concepts embodied therein. For example, the manual motion knob **163** may be replaced by any other control which allows velocity and direction control, for example by a button or knob which can be rotated or rocked to multiple positions corresponding to various velocities and directions of motions, or a set of buttons or knobs which allow the operator to separately select a desired velocity with one button or knob and a desired direction with another button or knob. Therefore, this specific embodiment is to be interpreted as exemplary and not limiting, with the scope of protection being determined solely from the following claims.

What is claimed is:

1. An injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, adapted for use with a syringe including an extender attached to said plunger, comprising:

a control circuit which causes said motor to move, said control circuit tracking the location of said motor while moving said motor, and

a memory storing an offset value representative of the length of the extender which is attached to said plunger, wherein

said control circuit computes a value indicative of the location of said plunger within said syringe by relating said stored offset value to the tracked location of said motor, and ceases motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

2. The injector of claim **1** further comprising

a display, and

a keypad usable by an operator to control said injector,

wherein said control circuit generates and stores said offset value by controlling said display to request, from an operator, information sufficient to compute the length of the extender which is attached to said plunger, monitoring keystrokes on said keypad to determine said information, deriving said offset value therefrom, and storing the derived offset value in said memory.

3. The injector of claim **1** further comprising

a detector located proximate to said syringe for detecting the length of the extender which is attached to said plunger from physical indicia on the syringe or extender and generating an electrical signal representative of the detected length, wherein

said control circuit is responsive to said electrical signal, and generates and stores an offset value corresponding to the detected length represented by said electrical signal.

4. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, adapted for use with a syringe including an extender attached to said plunger, comprising:

storing an offset value representative of the length of the extender which is attached to said plunger,

causing said motor to move,

tracking the location of said motor while moving said motor,

computing a value indicative of the location of said plunger within said syringe by relating said stored offset value to the tracked location of said motor, and

ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

5. The method of claim **4** further comprising

requesting, from an operator, information sufficient to compute the length of the extender which is attached to said plunger, and

deriving said offset value from said information from said operator.

6. The method of claim **4** further comprising

detecting the length of the extender which is attached to said plunger from physical indicia on the syringe or extender and generating an electrical signal representative of the detected length, and

deriving said offset value from the detected length represented by said electrical signal.

7. An injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at a distal end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to a syringe installed on said injector for detecting a physical indicia on said syringe related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the location of a plunger within said syringe relative to an end of said syringe, by relating said electrical signal to the tracked location of said motor.

8. The injector of claim **7** wherein said control circuit ceases motion of said motor and plunger when a location of said plunger computed by said control circuit indicates that said plunger has arrived at an end of said syringe.

9. The injector of claim **7** wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

10. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of

said syringe, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the location of a plunger within said syringe relative to an end of said syringe by relating said electrical signal to the tracked location of said motor.

11. The method of claim 10 further comprising:

ceasing motion of said plunger when a computed location of said plunger indicates that said plunger has arrived at an end of said syringe.

12. The method of claim 10 wherein said electrical signal represents the length of an extender which is attached to said plunger.

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Niehoff

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[54] **CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS**

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[51] **Int. Cl.**[6] **A61M 37/00**

[52] **U.S. Cl.** **604/155**; 604/151; 417/15; 417/63

[58] **Field of Search** 604/67, 131, 151, 604/154, 155; 417/15, 33, 42, 43, 445, 63

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,475,666	10/1984	Bilbrey et al.	604/155
4,529,401	7/1985	Leslie et al.	604/155
4,685,903	8/1987	Cable et al.	604/151
4,722,734	2/1988	Kolln	604/151
4,741,732	5/1988	Crankshaw	604/155
4,767,406	8/1988	Wadham et al.	604/155
4,838,857	6/1989	Strowe et al.	604/67
4,854,324	8/1989	Hirschman et al.	604/155
4,978,335	12/1990	Arthur, III .	
4,988,337	1/1991	Ito	604/154
5,034,004	7/1991	Crankshaw .	
5,078,683	1/1992	Sancoff et al.	604/67
5,135,507	8/1992	Haber et al.	604/187
5,236,416	8/1993	McDaniel et al. .	

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

160 303	11/1985	European Pat. Off. .	
164 904	12/1985	European Pat. Off. .	
364 010	4/1990	European Pat. Off.	604/151
482 677	4/1992	European Pat. Off. .	
523 343	1/1993	European Pat. Off. .	
WO89/06145	1/1988	WIPO .	

OTHER PUBLICATIONS

Medrad, Inc., *The First and Only True Injection System*, Medrad Mark V System Brochure.

Medrad, Inc., *A Quick Turn provides Added Convenience*, Medrad MCT Plus Front Load Injection System Brochure.

Medrad, Inc., *More than a Good Image*, Medrad MCT Injection System Brochure.

Medrad, Inc., *Enhanced CT Images. Enhanced CT Accuracy. Enhanced CT Control. etc. . .*, Medrad CT-201 Mark IV Flow controlled Injection System Brochure.

Declaration of James H. Goethel.

Declaration of Kenneth J. Niehoff.

(List continued on next page.)

Primary Examiner—Todd E. Manahan

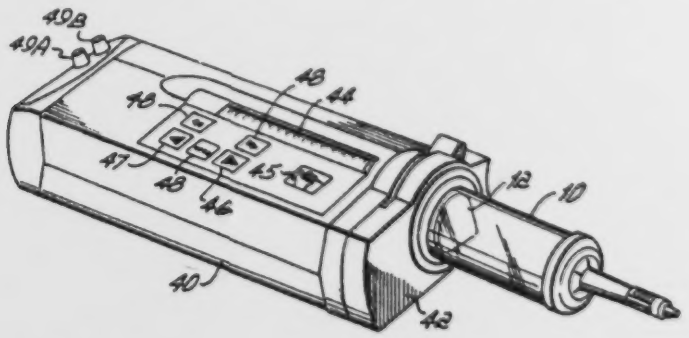
Attorney, Agent, or Firm—Wood, Herron & Evans, L.L.P.

[57] **ABSTRACT**

A computer-controlled injector of the type having a motor which advances and retracts a plunger located within a syringe housing toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject. Manual motion is induced by operating a manual motion control; the operator can manipulate the control to indicate the desired direction and velocity of motion. The manual motion control also has a locking mode in which manual motion of the plunger will continue once initiated without requiring the operator to continue manipulating the manual motion control. The injector performs injections in accordance with one of several pre-programmed protocols, and automatically tracks the fluid volume remaining. The injector compensates for plunger extenders found in some partially pre-filled syringes by applying a stored offset value to the computed plunger position.

28 Claims, 11 Drawing Sheets

Microfiche Appendix Included
(7 Microfiche, 613 Pages)



U.S. PATENT DOCUMENTS

5,242,408	9/1993	Jhuboo et al.	604/152
5,256,157	10/1993	Samiotes et al.	604/246
5,342,298	8/1994	Michaels et al.	604/65
5,354,287	10/1994	Wacks	604/232
5,356,393	10/1994	Haber et al.	604/222
5,383,858	1/1995	Reilly et al.	604/152
5,425,716	6/1995	Kawasaki et al. .	

OTHER PUBLICATIONS

Declaration of Dwayne Crawford.

Liebel–Flarsheim Company, 2111 E. Galbraith Road, Cincinnati, OH 45215, Angiomat 6000, Brochure, copyright 1987.

Liebel–Flarsheim Company, 2111 E. Galbraith Road, Cincinnati, OH 45215, *Angiomat CT*, Brochure, copyright 1988.

EZ–EM, Inc., 717 Main Street, Westbury, NY 11590, *PercuPump*, Brochure, copyright 1990.

Siemens Aktiengesellschaft, *Microprocessor–Controlled Angiography High Pressure Pulsed Injector*, Siemens Simtrac C Brochure.

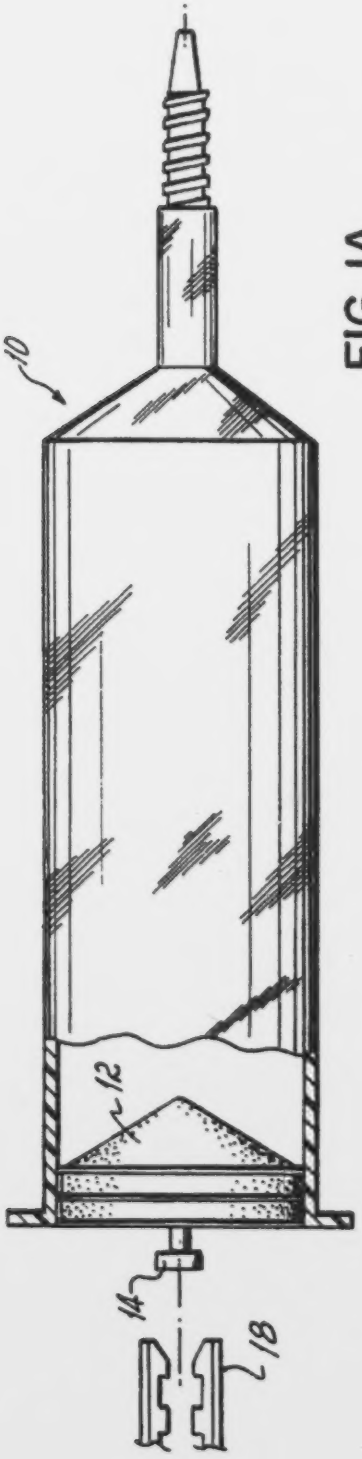


FIG. IA

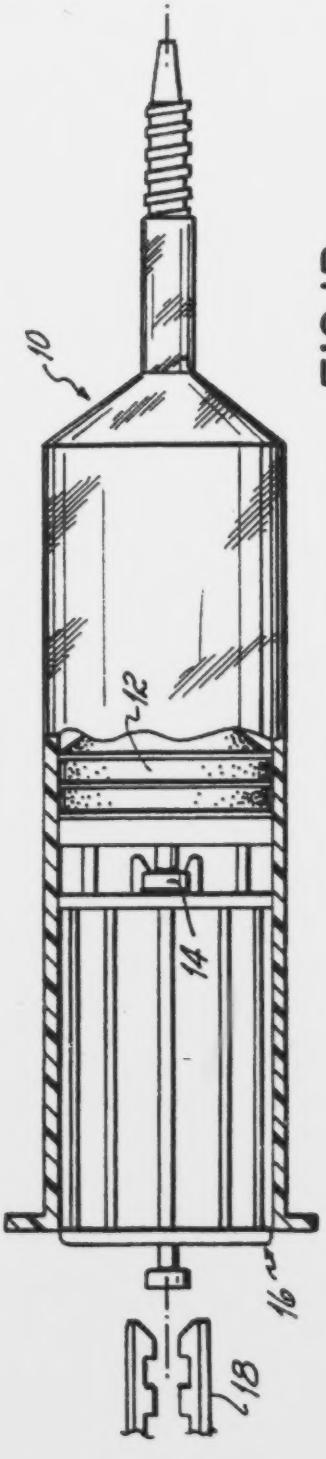


FIG.IB

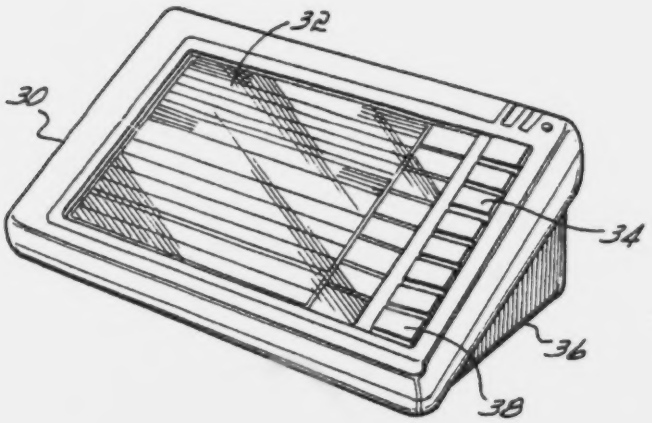


FIG. 2A

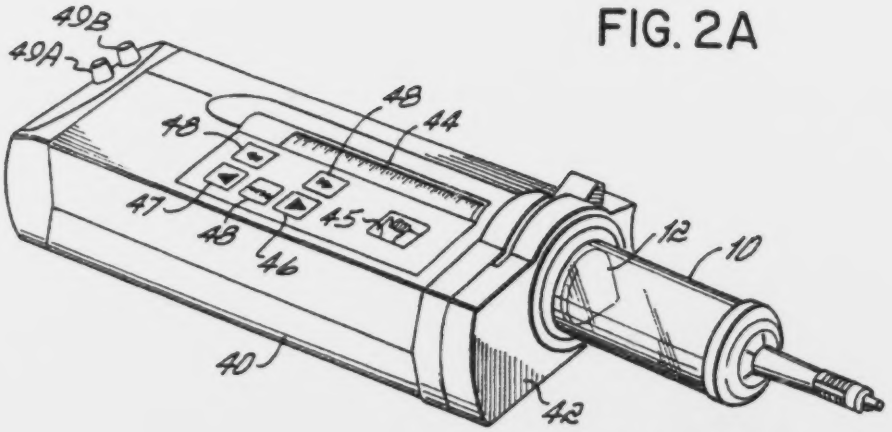


FIG. 2B

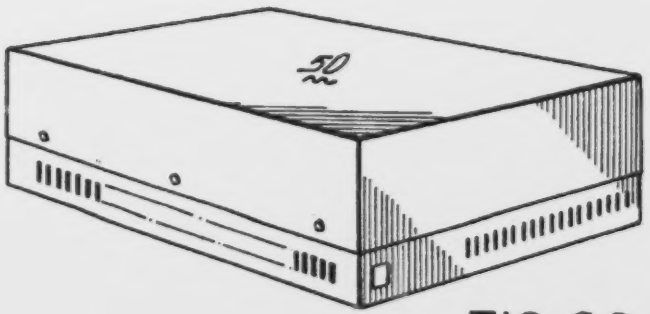


FIG. 2C

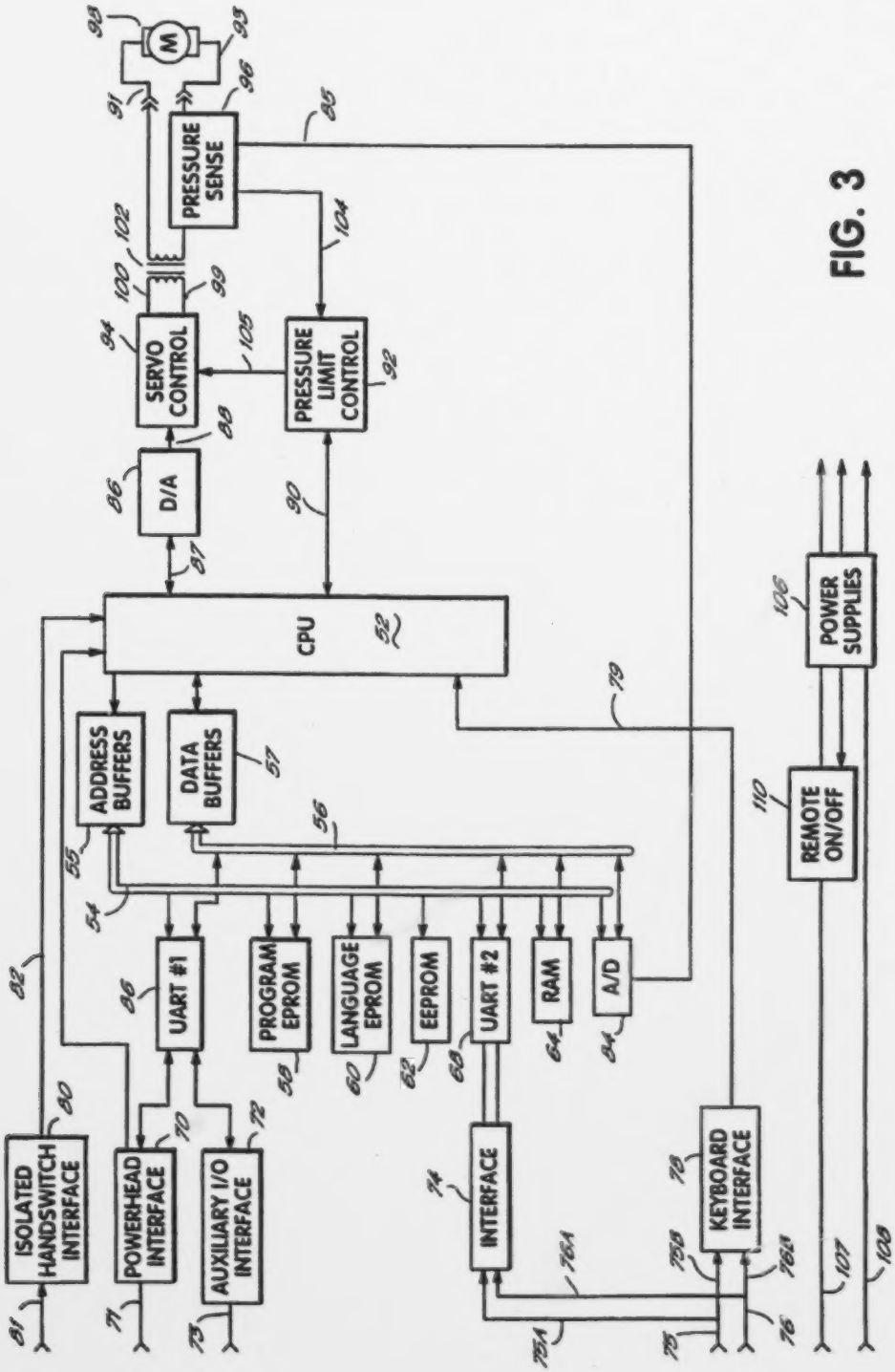

M
PRESSURE SENSE
SERVO CONTROL
PRESSURE LIMIT CONTROL
D/A
CPU
ADDRESS BUFFERS
DATA BUFFERS
UART #1
PROGRAM EPROM
LANGUAGE EPROM
EEPROM
UART #2
RAM
A/D
ISOLATED HANDSWITCH INTERFACE
POWERHEAD INTERFACE
AUXILIARY I/O INTERFACE
INTERFACE
KEYBOARD INTERFACE
POWER SUPPLIES
REMOTE ON/OFF

FIG. 3

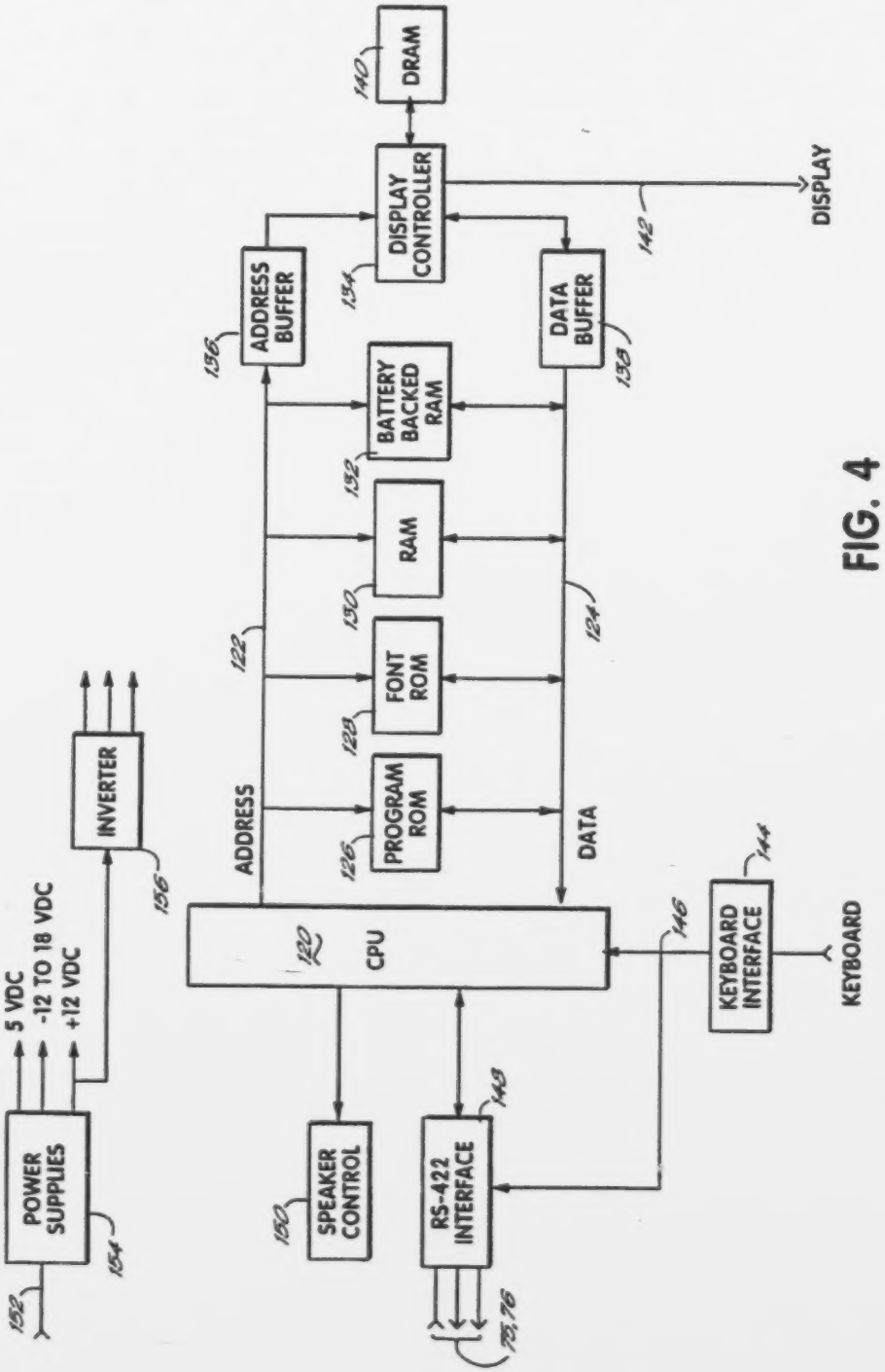

DRAM
140
DISPLAY CONTROLLER
134
DISPLAY
142
ADDRESS BUFFER
136
DATA BUFFER
138
BATTERY BACKED RAM
132
RAM
130
FONT ROM
128
PROGRAM ROM
126
ADDRESS
122
DATA
124
CPU
120
INVERTER
156
5 VDC
-12 TO 18 VDC
+12 VDC
POWER SUPPLIES
154
152
SPEAKER CONTROL
150
RS-422 INTERFACE
148
75,76
KEYBOARD INTERFACE
144
146
KEYBOARD

FIG. 4

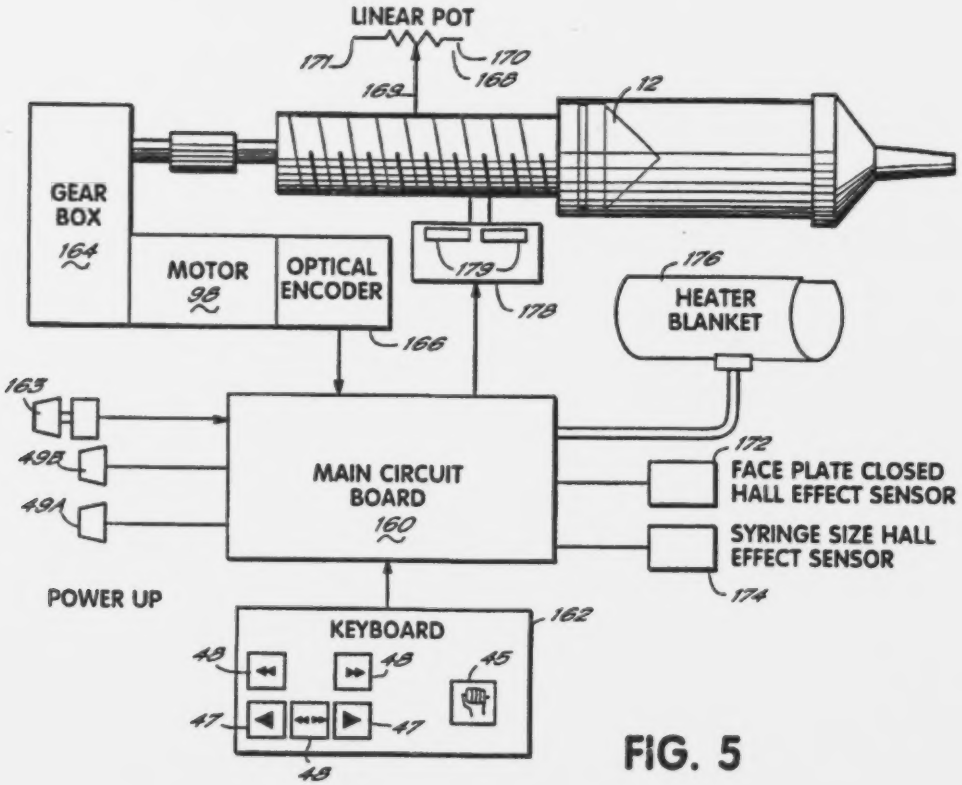

LINEAR POT
171
170
168
169
12
GEAR BOX
164
MOTOR
98
OPTICAL ENCODER
179
178
176
HEATER BLANKET
166
163
49B
49A
MAIN CIRCUIT BOARD
160
172
FACE PLATE CLOSED HALL EFFECT SENSOR
SYRINGE SIZE HALL EFFECT SENSOR
174
POWER UP
KEYBOARD
162
43
43
45
47
47
43

FIG. 5

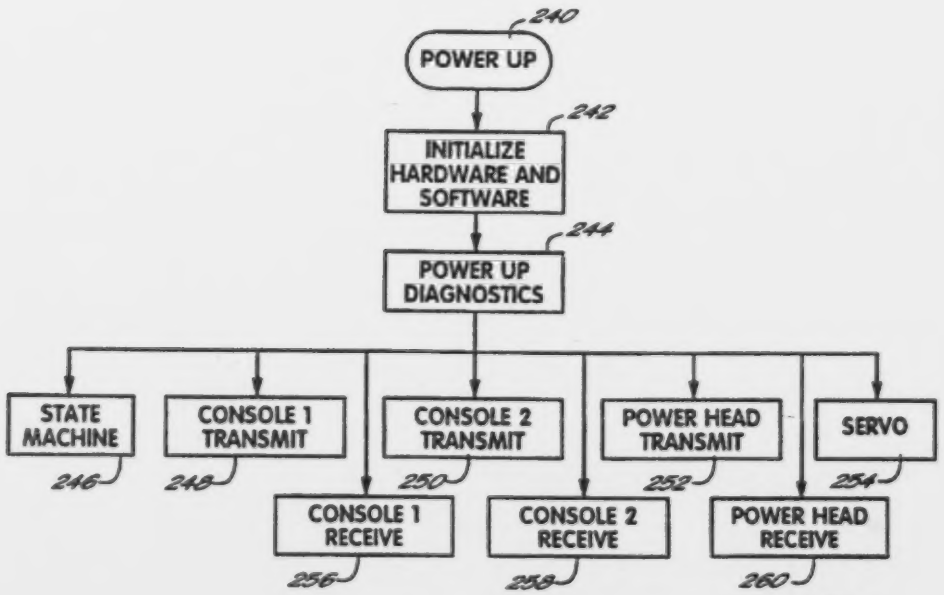

240
POWER UP
242
INITIALIZE HARDWARE AND SOFTWARE
244
POWER UP DIAGNOSTICS
STATE MACHINE
246
CONSOLE 1 TRANSMIT
248
CONSOLE 2 TRANSMIT
250
POWER HEAD TRANSMIT
252
SERVO
254
CONSOLE 1 RECEIVE
256
CONSOLE 2 RECEIVE
258
POWER HEAD RECEIVE
260

FIG.7A

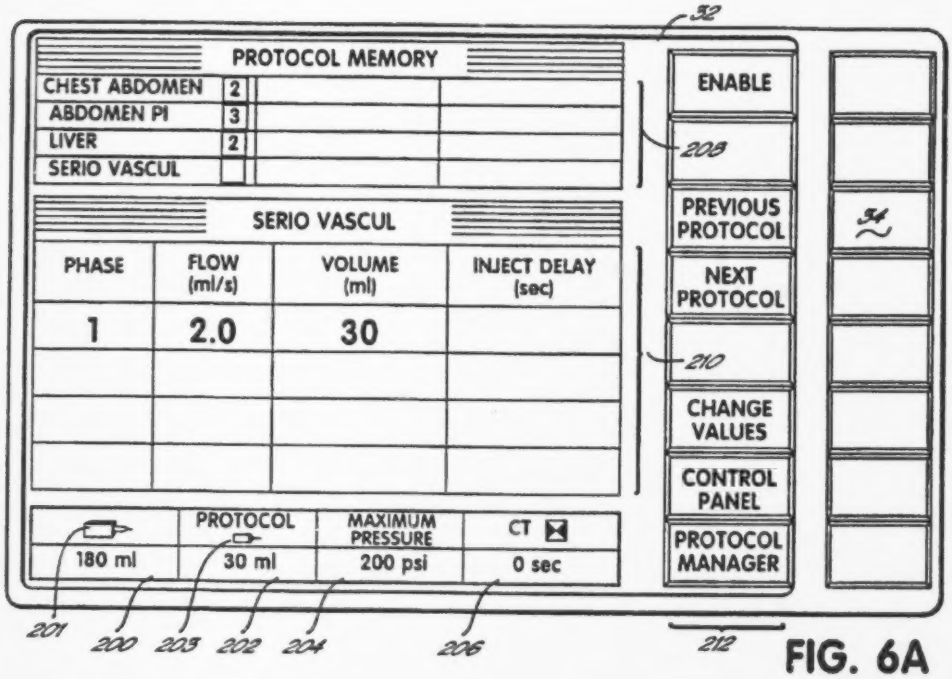

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
180 ml
PROTOCOL
30 ml
MAXIMUM PRESSURE
200 psi
CT
0 sec
ENABLE
208
PREVIOUS PROTOCOL
NEXT PROTOCOL
210
CHANGE VALUES
CONTROL PANEL
PROTOCOL MANAGER
34
201
200
203
202
204
206
212

FIG. 6A

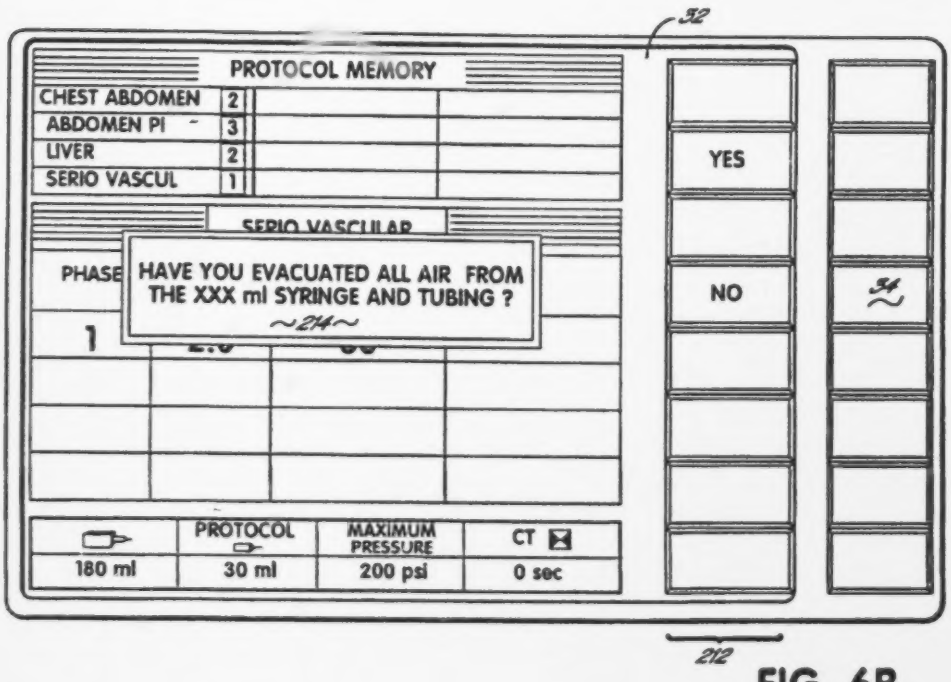

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
HAVE YOU EVACUATED ALL AIR FROM THE XXX ml SYRINGE AND TUBING ?
214
PHASE
1
180 ml
PROTOCOL
30 ml
MAXIMUM PRESSURE
200 psi
CT
0 sec
YES
NO
34
212

FIG. 6B

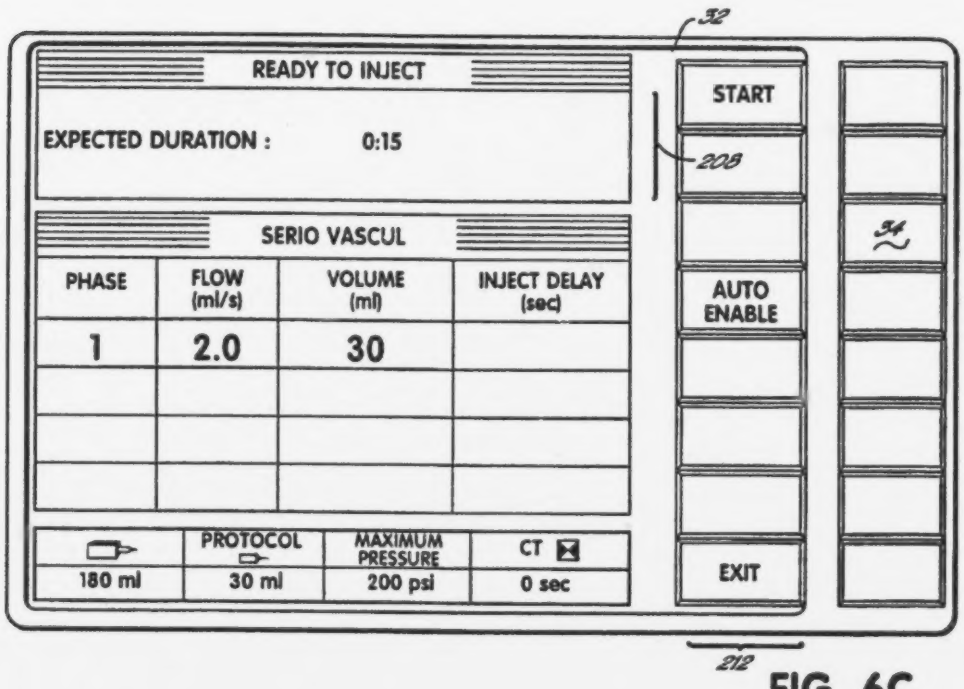

32
READY TO INJECT
EXPECTED DURATION : 0:15
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
START
208
34
AUTO ENABLE
EXIT
212

FIG. 6C

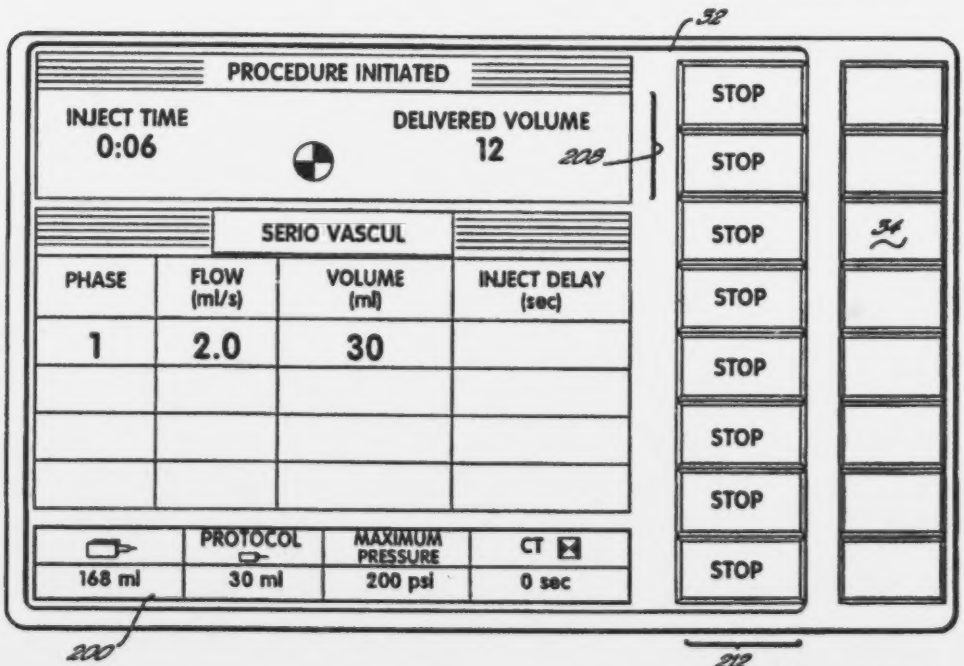

32
PROCEDURE INITIATED
INJECT TIME
0:06
DELIVERED VOLUME
12
208
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
168 ml
30 ml
200 psi
0 sec
STOP
34
200
212

FIG. 6D

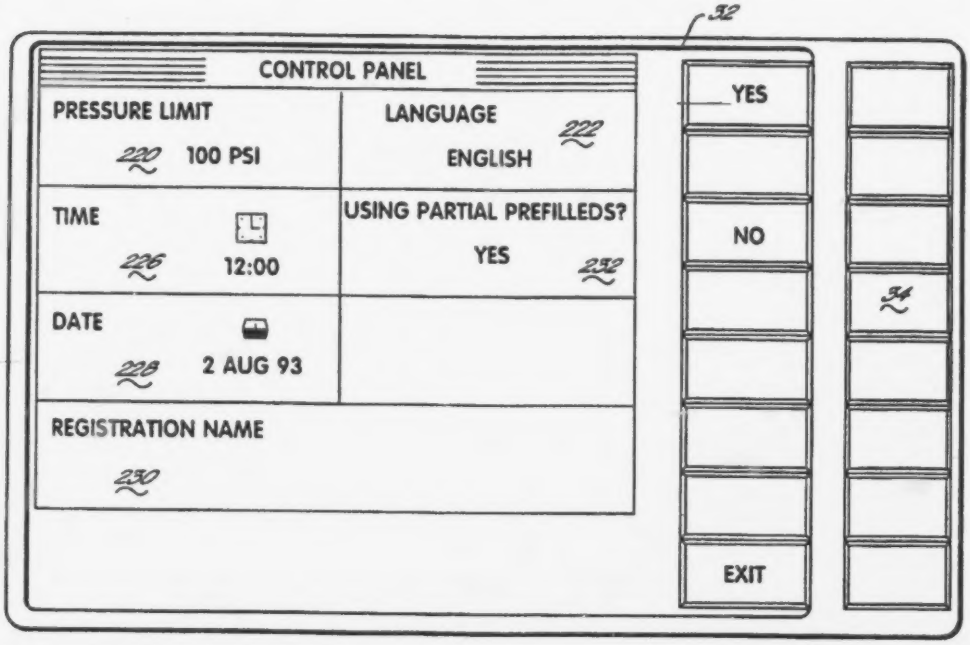

32
CONTROL PANEL
PRESSURE LIMIT
220
100 PSI
LANGUAGE
222
ENGLISH
TIME
226
12:00
USING PARTIAL PREFILLEDS?
YES
232
DATE
228
2 AUG 93
REGISTRATION NAME
230
YES
NO
EXIT
34
212

FIG. 6E

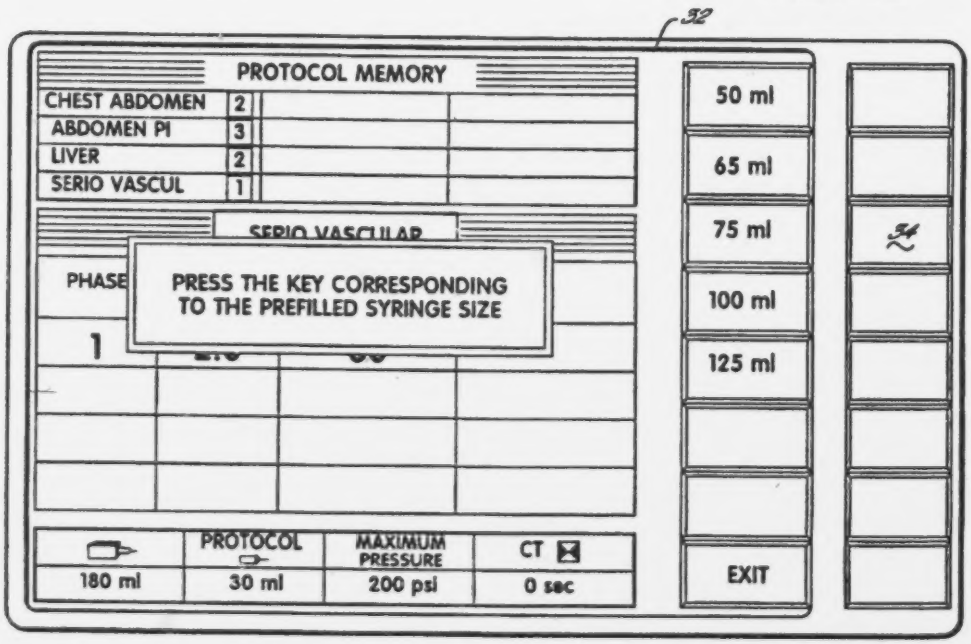

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
PRESS THE KEY CORRESPONDING TO THE PREFILLED SYRINGE SIZE
PHASE
1
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
50 ml
65 ml
75 ml
100 ml
125 ml
EXIT
34

FIG. 6F

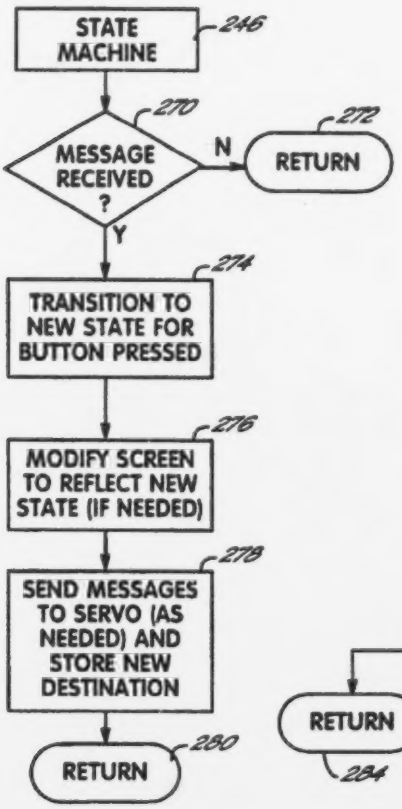

STATE MACHINE
246
270
MESSAGE RECEIVED ?
N
272
RETURN
Y
274
TRANSITION TO NEW STATE FOR BUTTON PRESSED
276
MODIFY SCREEN TO REFLECT NEW STATE (IF NEEDED)
278
SEND MESSAGES TO SERVO (AS NEEDED) AND STORE NEW DESTINATION
RETURN
280

FIG.7B

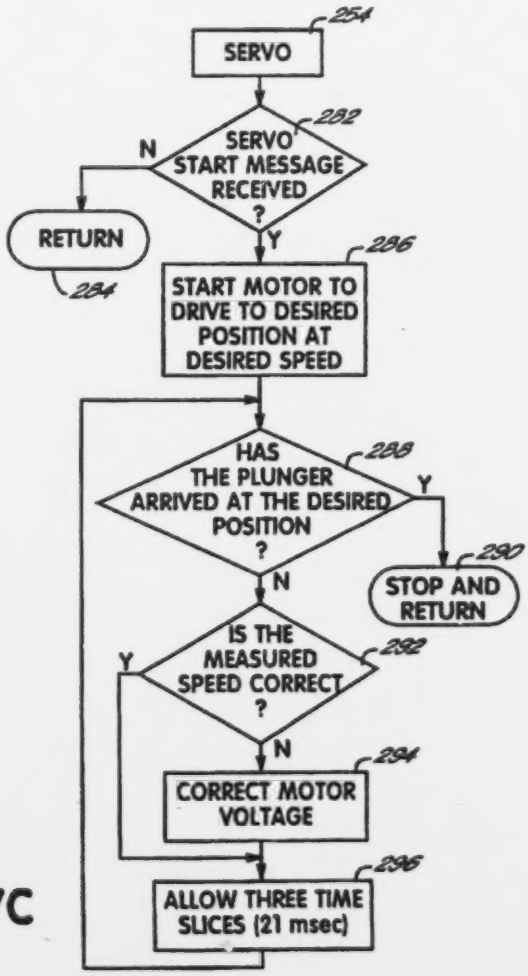

SERVO
254
282
SERVO START MESSAGE RECEIVED ?
N
RETURN
284
Y
286
START MOTOR TO DRIVE TO DESIRED POSITION AT DESIRED SPEED
288
HAS THE PLUNGER ARRIVED AT THE DESIRED POSITION ?
Y
290
STOP AND RETURN
N
292
IS THE MEASURED SPEED CORRECT ?
Y
N
294
CORRECT MOTOR VOLTAGE
296
ALLOW THREE TIME SLICES (21 msec)

FIG.7C

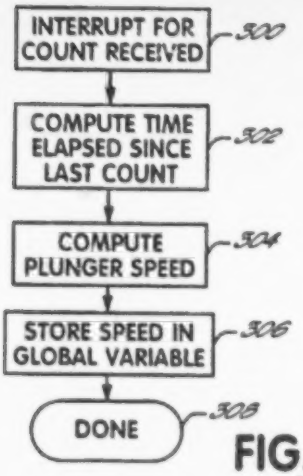

INTERRUPT FOR COUNT RECEIVED
300
COMPUTE TIME ELAPSED SINCE LAST COUNT
302
COMPUTE PLUNGER SPEED
304
STORE SPEED IN GLOBAL VARIABLE
306
DONE
308

FIG.7D

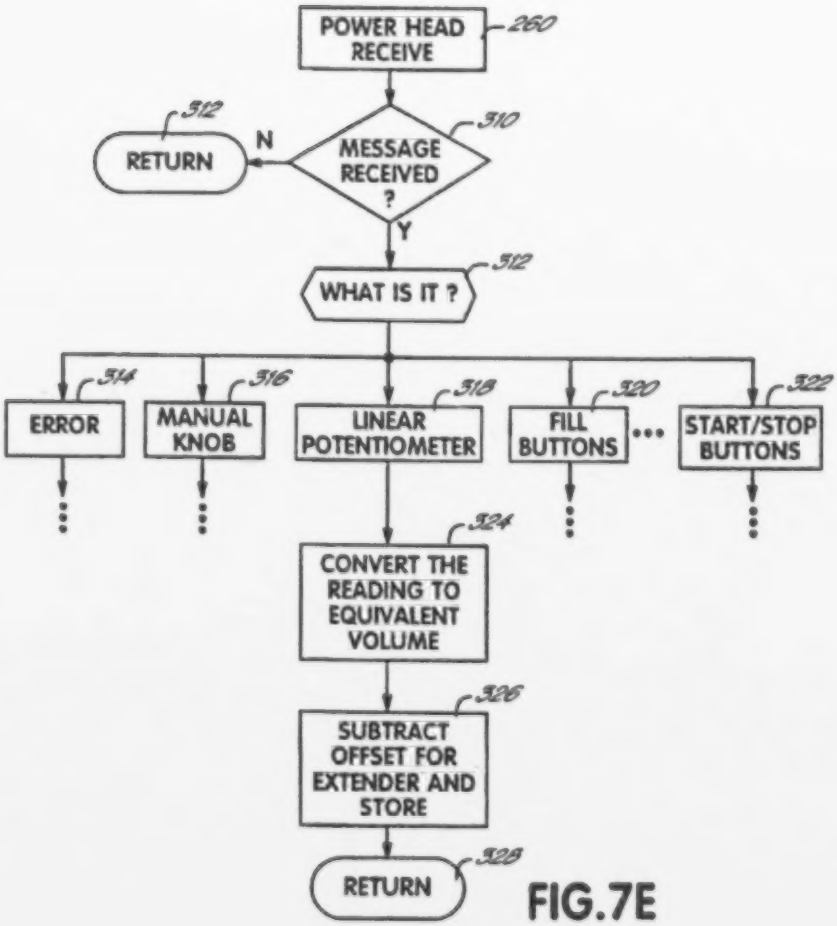

POWER HEAD RECEIVE
260
MESSAGE RECEIVED ?
310
N
RETURN
312
Y
WHAT IS IT ?
312
ERROR
314
MANUAL KNOB
316
LINEAR POTENTIOMETER
318
FILL BUTTONS
320
START/STOP BUTTONS
322
CONVERT THE READING TO EQUIVALENT VOLUME
324
SUBTRACT OFFSET FOR EXTENDER AND STORE
326
RETURN
328

FIG.7E

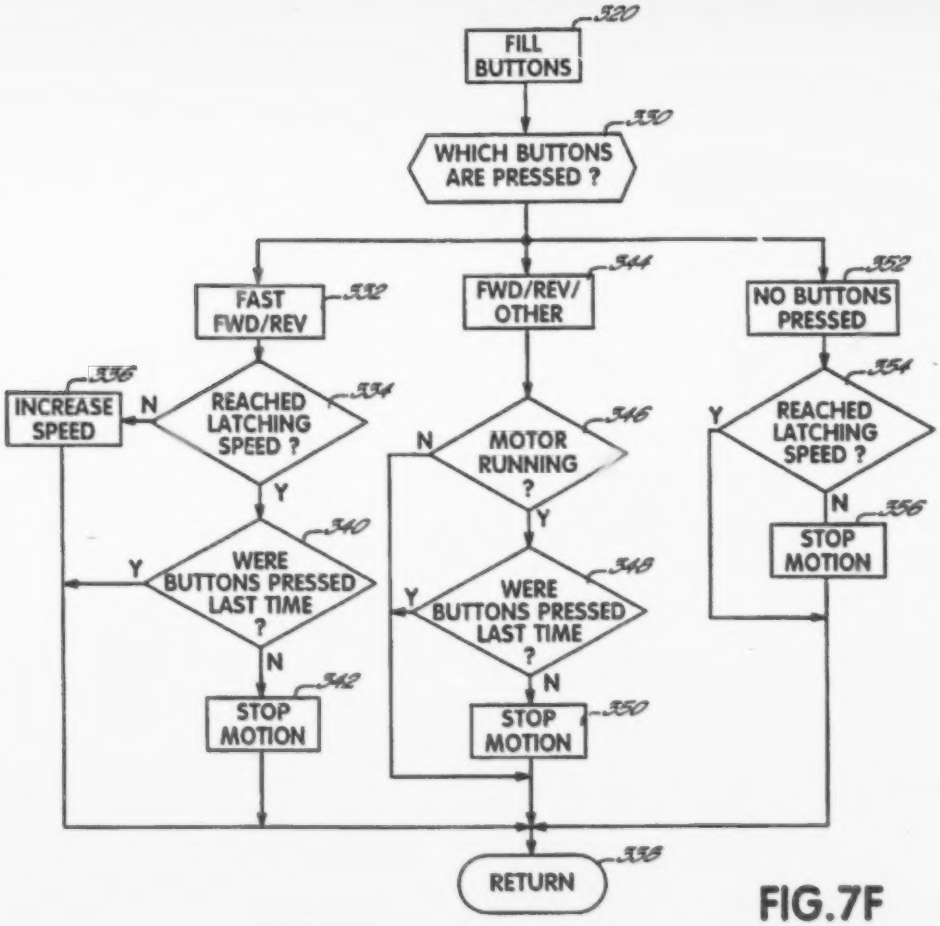

320
FILL BUTTONS
330
WHICH BUTTONS ARE PRESSED ?
FAST FWD/REV
332
FWD/REV/ OTHER
344
NO BUTTONS PRESSED
352
INCREASE SPEED
336
N
REACHED LATCHING SPEED ?
334
Y
N
MOTOR RUNNING ?
346
Y
N
REACHED LATCHING SPEED ?
354
Y
N
STOP MOTION
356
Y
WERE BUTTONS PRESSED LAST TIME ?
340
N
STOP MOTION
342
Y
WERE BUTTONS PRESSED LAST TIME ?
348
N
STOP MOTION
350
RETURN
338

FIG.7F

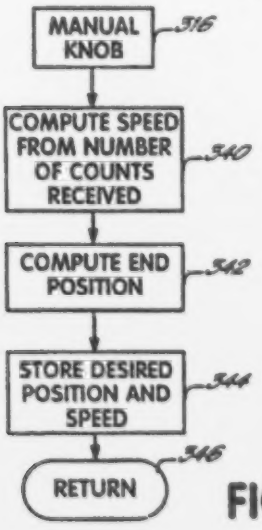

MANUAL KNOB
316
COMPUTE SPEED FROM NUMBER OF COUNTS RECEIVED
340
COMPUTE END POSITION
342
STORE DESIRED POSITION AND SPEED
344
RETURN
346

FIG.7G

CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation application of application Ser. No. 08/494,795 filed on Jun. 26, 1995, for CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS which issued Sep. 2, 1997 as U.S. Pat. No. 5,662,612 which is a continuation of application Ser. No. 08/157,823 filed on Nov. 24, 1993, which is now abandoned.

This application is related to previously-filed U.S. patent application Ser. No. 07/881,782 of Charles S. Neer et al., filed May 11, 1992 for METHOD AND APPARATUS FOR INJECTING FLUID INTO ANIMALS AND DISPOSABLE FRONT LOADABLE SYRINGE THEREFOR, which is assigned to the same entity as this application.

REFERENCE TO MICROFICHE APPENDIX

A microfiche appendix is attached to this application (7 pages, 613 frames). The software in this appendix is subject to copyright protection. The copyright owner has no objection to reproduction of the appendix in the form that it appears in the U.S. Patent and Trademark Office, but reserves all other rights under copyright law.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as radiopaque media (contrast fluid) used to enhance x-ray or magnetic images, from a syringe, through a tube, and into an animal subject. Injectors are typically provided with an injector unit, adjustably fixed to a stand or support, having a plunger drive that couples to the plunger of the syringe and may move the plunger forward to expel fluid into the tube, or move the plunger rearward to draw fluid into the syringe to fill it.

Injectors often include control circuits for controlling the plunger drive so as to control the rate of injection and amount of fluid injected into the subject. Typically, the control circuit includes one or more manual switches which allow a user to manually actuate the plunger drive to move the plunger into or out of the syringe; typically the user holds down a "forward" or "reverse" drive switch to move the plunger in the indicated direction.

To reduce the risk of infection, in a typical injection procedure the syringe is only used once, and is disposed after use. In some cases, the syringe is inserted into the injector empty. The empty syringe is filled by retraction of the plunger while the interior of the syringe communicates with a supply of the contrast fluid via an injection tube connected between the nozzle of the syringe and the supply of media. Then, bubbles are removed from the syringe, and the injection is performed. At the end of the procedure, the syringe plunger typically is forward, as is the plunger drive.

In some injectors, the syringe can only be removed or replaced while the plunger drive is fully retracted. As illustrated in FIG. **1A**, typically an empty syringe **10** is filled with sterile air, with the plunger **12** at the fully retracted position as shown. The plunger drive includes a jaw **18** designed to engage and disengage a button **14** on the rear side of the plunger while the plunger is in this fully-retracted position. Before an empty new syringe can be filled, it is necessary that the plunger be moved fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. Thus, the reloading operation can involve fully retracting the plunger drive to allow removal and replacement of the syringe, then fully advancing the plunger drive and plunger to expel air from the syringe, and then retracting the plunger drive and plunger to fill the syringe. These lengthy, manual movements of the plunger and drive are time consuming.

The above-referenced patent application describes a front-loading injector in which a syringe can be replaced even though the plunger drive is not fully retracted. This injector substantially reduces the number of plunger drive movements necessary to prepare a syringe for a new injection; after an injection, the syringe can be removed and replaced without moving the drive from its fully-advanced position. (The plunger drive jaw **20** can engage and disengage button **14** regardless of the position of the plunger.) After the syringe is replaced, the drive is retracted, filling the syringe for a new injection. Thus, to ready the injector for a new injection, the plunger drive is manually moved once rather than three times.

Another recent development is the use of pre-filled disposable syringes. A pre-filled syringe also reduces the number of manual plunger drive movements necessary to prepare the injector for a new injection. After an injection, the plunger drive is fully retracted, the used syringe is removed and replaced with the pre-filled syringe, and the injector is ready for a new injection. Thus, again, the plunger drive is manually moved once rather than three times.

To prevent infection, contrast media remaining in a syringe after an injection must be discarded. However, contrast media is relatively expensive. For this reason, when preparing for an injection, an empty syringe is filled with only as much media as will be needed for the next injection. For the same reason, pre-filled syringes are sold in a number of capacities, e.g. ranging from 60 to 125 milliliters, allowing the operator preparing for an injection to select a syringe containing only as much media as is needed for the injection.

A typical pre-filled syringe is illustrated in FIG. **13**. In many respects, the pre-filled syringe is identical to the empty syringe shown in FIG. **1A**. The barrels **10** and plungers **12** have the same size and profile in both syringes (injectors now in use accommodate only a few FDA approved syringe sizes, e.g., a 200 milliliter size and a 125 milliliter size, so all syringes use these sizes). Furthermore, both syringes have a button **14** which is initially located at the end of the barrel **10** (thus, both syringes are compatible with injectors which are designed to grip a button at the end of the syringe). The main difference is that in the pre-filled syringe of FIG. **1B**, the initial location of the plunger **12** is in the middle of the syringe (thus reducing the initial volume of the pre-filled syringe). An extender **16** is attached to button **14** of the plunger, and provides a second button **18** at the end of the syringe which can be gripped by the injector.

SUMMARY OF THE INVENTION

As noted above, at the present state of the art, preparing an injector for an injection requires at least one manual movement of the plunger drive into or out of the syringe barrel, and as many as three such movements. This operation is tedious and inefficient, not only because of the time consumed, but also because the operator must press and hold manual movement switches to produce the movement, and thus is physically tied to the injector and cannot use this time to make other preparations.

In accordance with one embodiment of the present invention, the plunger drive controller has a locked mode in which motion, initially requested by pressing a manual

movement switch, will continue whether or not the operator continues pressing the switch, until the plunger drive reaches its fully-advanced or fully-retracted position. Thus, once the controller has entered the locked mode, the operator may release the manual switch and the desired movement, either advancement or retraction, will continue while the operator makes other preparations for the next injection.

In preferred embodiments, the operator causes the controller to enter the locked mode by pressing the manual movement switch for a predetermined period of time. For safety, the manual movement switch may comprise two buttons which must be simultaneously pressed to produce movement. Movement is initiated by pressing both buttons. While both buttons are held down, the plunger drive controller increases the velocity of movement until the velocity reaches a maximum, at which time the plunger drive controller enters the locked mode. If one button is released before the controller reaches maximum velocity and enters the locked mode, the movement will continue, but at a constant velocity. If the second button is released, the movement will stop. Alternatively, if the controller has reached maximum velocity and entered the locked mode, movement will continue even if both buttons are released; however, if thereafter either button is pressed, movement stops. The controller can provide visual feedback, for example via a light which blinks during motion and lights steadily when the controller is in the locked mode. This light may itself move in synchronism with the plunger drive to provide further feedback on the speed of motion.

As noted, the plunger drive controller is typically manually controlled by means of a switch which, when depressed, causes the plunger drive to move in one of two directions. In accordance with a second aspect of the invention, manual control is improved by providing an adjustment allows the operator to adjust the rate at which the plunger drive moves or accelerates. This permits the operator to customize the operation of the plunger drive controller to enhance individual comfort.

In preferred embodiments, the manual control comprises a wheel which, when rotated, causes the plunger drive to move at a speed which is proportional to the speed of rotation. Alternatively, the manual control may be a forward switch and a reverse switch which cause the plunger drive to move in the indicated direction at a programmable velocity or acceleration.

To operate effectively, the plunger drive controller must determine the location of the plunger **12** relative to the ends of the syringe **10** so that, for example, the controller can determine the amount of contrast media remaining in the syringe. This can be done by a sensor which detects the location of the plunger drive jaw **20**, which is coupled directly to and moves with the plunger **12**. However, a pre-filled syringe may include an extender **16** which changes the relative location of the plunger **12** and the plunger drive jaw **20**, leading to malfunction in the plunger drive controller. In accordance with a third aspect of the invention, malfunction is avoided by storing an offset value representative of the length of the extender **16**, and applying this offset value to the computed drive jaw position.

In preferred embodiments, the offset value may be computed by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value. The controller may be configurable so that this query is not made (for example, if the injector will not be used with pre-filled syringes, and therefore the offset value will not change). Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

These and other aspects will be further illustrated in the following detailed description with reference to the attached drawings, in which:

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1A and 1B are side, partial cut-away views of an empty syringe and a pre-filled syringe, respectively.

FIGS. 2A, 2B and 2C respectively illustrate the console, powerhead, and powerpack of an injector.

FIGS. **3**, **4**, and **5** are electrical and electrical-mechanical block diagrams of the powerpack, console and powerhead, respectively.

FIGS. 6A, 6B, 6C, 6D, 6E and 6F are illustrations of displays produced by the console in operation of the injector.

FIGS. 7A, 7B, 7C, 7D, 7E, 7F and 7G are flow charts illustrating the software operating within the power pack.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 2A, 2B and 2C, an injection system according to the invention includes three main components, a console **30**, a powerhead **40** and a powerpack **50**.

The console **30** comprises a liquid crystal display **32** of the type used in notebook computers (e.g., a display sold by Sharp Electronics Corp. of 5700 N.W. Pacific Rim Blvd., Camas, Wash. 98607 as part number IL64P62), coupled to an eight key keypad **34** within a housing **36**. As is further elaborated below, display screens presented on display **32** provide injection information and present the user with menus of one or more possible operations, each operation associated with one of the keys on keypad **34**.

The powerhead **40** includes a mount **42** (such as that described in the above-referenced patent application) which accepts a syringe **10** for an injection. The powerhead includes a plunger drive motor (not shown) for moving plunger **12** forward into and rearward out of syringe **10** during an injection in accordance with a preprogrammed sequence, or protocol, selected by the operator by operation of the console **30**.

The location and movement of the plunger drive is indicated by a light emitting diode (LED) which is mounted to the plunger drive and is visible to the operator through a graduated window **44** in the side of the powerhead **40**. As noted below, this LED flashes when the plunger drive is moving, and lights steadily when the plunger drive has been manually locked into forward or reverse motion in the manner described below.

The side of the powerhead **40** includes six pushbuttons: a start/stop button **45**, a forward manual motion button **46**, a reverse manual motion button **47**, and an enable/accelerate button **48**. The three enable/accelerate buttons **48** perform the same function; there are three buttons instead of one to improve operator accessibility.

The start/stop button **45** is used to start an injection protocol selected at the console, or to stop and restart an injection. During an injection, all of the eight buttons on the keypad **34** of the console **30** will perform an identical start and stop function. Furthermore, a remote handswitch (not shown) may be connected to the powerpack **50** (see below) to perform a start and stop function. (For this reason, the start/stop button **45** includes a picture of a handswitch.) To manually move the plunger drive, the operator must simul-

taneously press a motion button **46** or **47** and an enable button **48**. This is a safety feature which reduces the risk of accidental movement of the plunger. If the operator presses the forward button **46** and any of the three enable buttons **48**, the plunger will begin forward motion; conversely, if the operator presses the reverse button **47** and any of the three enable buttons **48**, the plunger will begin reverse motion. Once motion is initiated in either direction, the operator may release one of the buttons; motion will be maintained at a constant velocity in the same direction so long as any one of the five buttons **46**, **47** or **48** is held down. If, instead, after initiating motion in one direction, the operator continues to hold down an enable button **48** and a motion button **46** or **47**, motion will not only be maintained in the same direction, but will be accelerated in this direction until either the operator releases one of the buttons or a maximum velocity is achieved. At any time during the acceleration, the operator may release one of the buttons and hold down the other, and the motion will continue at the same velocity without acceleration. Thereafter, the operator can re-depress the released button, at which time acceleration will begin again.

If the velocity of motion increases to a maximum value, the plunger drive controller (described in more detail below) will enter a locked mode. In this locked mode, movement will continue at the maximum velocity in the same direction even if the operator releases all of the buttons. This frees the operator to perform other tasks when preparing for an injection without being forced to hold manual buttons on the injector until the plunger drive has made the lengthy transition to its fully-advanced or fully-retracted position.

For safety reasons, the locked mode can be terminated readily. If the operator has entered the locked mode and thereafter released all of the buttons, if at any time thereafter any of the buttons is pressed, the plunger drive controller will exit the locked mode and terminate motion.

Two lights **49A** and **49B** mounted on the rear of the powerhead **40** indicate the status of operation of the injector. Light **49A** is an injecting/fault indicator. This light glows while an injection is in process. It will flash if an error is detected. Light **49B** is an enabled indicator. It glows when the injector has been enabled and is ready to perform an injection protocol.

The rear end of the powerhead **40** (opposite mount **42**) includes a jog wheel or switch (not shown in FIG. 2B, see **163**, FIG. **5**) used, in the manner described below, to manually activate motion of the plunger drive.

The powerpack **50** illustrated in FIG. 2C contains electronics which communicate with the console **30** and powerhead **40** to perform the functions described above. The powerpack is connected to the console **30** and powerhead **40** by standard computer communications cables (not shown). Signals carried on these cables are interfaced to circuitry inside of the powerhead, console, and powerpack in a manner described below.

As shown in FIG. **3**, the circuitry in the powerpack includes a central processing unit (CPU) **52** which controls the operations of the powerhead **40** and console **30**. The CPU is preferably a programmable microprocessor such as the MC68332FN microprocessor, manufactured by Motorola, 2110 East Elliot, Tempe, Ariz. 85284. This microprocessor is a member of the 68000 family of microprocessors and features multitasking support; it is designed for use in so called "embedded" environments such as the circuit described herein, and therefore has more than the usual number direct-wired input-output ports.

The CPU connects to an address bus **54** for addressing a number of memory and communications components and a data bus **56** for retrieving and/or sending data from and to these components. Buffers **55** and **57** aid CPU **52** in interfacing to the address and data busses, respectively. Each of the elements connected to the address and data busses are briefly described below.

An erasable programmable read-only memory (EPROM) **58** connected to data bus **56** contains the program software which operates the CPU **52**. The EPROM contains an operating system, which performs low-level management of the CPU and its communications with other circuits, and a custom program for controlling the console and powerhead to perform injection protocols. In one embodiment, the operating system software is the USX68K operating system, a multi-tasking operating system for 68000 series microprocessors sold by U.S. Software of 14215 N.W. Science Park Drive, Portland, Oreg., 97229, and the custom program is written in the "C" programming language. This custom program is described below, and a copy of the "C" language source code for the custom program appears in the appendix to this application.

A second EPROM **60** connected to data bus **56** contains language information used by the program software in EPROM **56** when generating displays for presentation on the display **32** (FIG. **2A**). As will be further elaborated below, the display screens presented on the display **32** include textual descriptions of actions being taken by the injector, and menu selections which the operator can select. The textual portions of these display elements are stored in the language EPROM **56**, from which they are retrieved and inserted into a template as CPU **52** is producing a display screen. Preferably, the language EPROM contains multiple versions of each textual insert, representing different languages, so that the operator can, through menu choices entered at the console keypad **34**, choose a preferred language in which to generate screen displays. An exemplary set of languages suitable for the North American and European markets would be English, German, French and Spanish.

A third, electrically erasable and programmable read only memory (EEPROM) **62** is attached to the data bus. EEPROM **62** stores data in a non-volatile manner (so that it will not be lost when the power is turned off). Among other things, EEPROM **62** stores preprogrammed injection protocols. These protocols are created and stored by the user as desired (details are reviewed with reference to FIG. **6A**, below). In addition, EEPROM **62** stores calibration information, used by CPU **52** in interpreting fluid pressure and plunger position information which it receives while performing an injection. Further, EEPROM **62** stores information on the most recently completed injection, such as the injection time and volume, so that this information may be retrieved by the operator. EEPROM **62** also stores operator preference data entered by the operator into the console (see FIG. **6E**, below). This includes the preferred display language, time, and date formats. Moreover, EEPROM **62** stores operating parameters such as a programmable pressure limit, and a flag (used in the manner described below) indicating whether the injector will be used with partially pre-filled syringes of the kind illustrated in FIG. **1B**. Finally, EEPROM **62** stores the registered name and/or number of the machine owner, to facilitate service and on-line customer support.

Data bus **56** is also connected to a random access memory (RAM) **64** which is used by the operating system to store a stack of register values generated during CPU operations and machine state information corresponding to currently inactive processes running on the CPU. The application

software uses the remaining space in RAM **64** (as managed and allocated by the operating system) to store variables computed and manipulated during operation of the injector.

Most communications between CPU **52** and the powerhead **40** and console **30** flow through one of two universal asynchronous receiver/transmitters (UARTs) **66**, **68** which are connected to the data bus. A UART is a communications circuit, generally available in integrated circuit form, which collects and buffers incoming and outgoing information to enable asynchronous communications between processors or computing systems over a data link. A suitable UART is the MC68681, sold by Motorola. The first UART **66** is responsible for communications with the powerhead circuitry (see FIG. **5**, below), which pass through an interface **70** and a communications cable **71** connected to the powerhead. (However, pulses from the optical encoder **166** on the powerhead (FIG. **5**, below) travel directly from interface **70** along line **71** to an interrupt input on the CPU **52**.) UART **66** also handles communications with an auxiliary interface **72**, which can be coupled through a communications cable **73** to a printer to allow CPU **52** to print records of an injection. Alternatively, interface **72** (or another, similar interface) can be used to attach CPU **52** to a remote computer or other external device to allow remote monitoring and/or control of the injector.

The second UART **68** is responsible for communication with the console **30** (FIG. **2A**). Two consoles **30** can be connected to the powerpack via cables **75**, **76**.

Cables **75** and **76** carry data representing keystrokes and screen activity between the powerpack **50** and console **30**. This data is encoded in a communications protocol and transmitted in accordance with the RS422 standard. The encoded data is carried via lines **75** and **76** to interface **74** which encodes and decodes transmissions for a second UART **68**. UART **68** routes keystrokes received by either console via interface **74** to CPU **52** via the data bus **56**, and further routes display information produced by CPU **52** to interface **74** for transmission to the consoles via lines **75A** and **76A**.

Cables **75** and **76** also include, on separate conductors, lines **75B** and **76B**, which carry logical signals corresponding to key **38** (FIG. **2A**) of each console keyboard. As elaborated below, the software driving the console displays is written so that key **38** is the most frequently used key—depending on the screen being displayed, key **38** will function as an "Exit" key to depart the screen, an "Enter" key to accept a value or selection and depart the screen, or a "Disable" or "Cancel" key to terminate an operation. (Exemplary screens are discussed below with reference to FIGS. **6A–6F**.) Because key **38** is the most frequently used key, and because key **38** is used for time-sensitive input such as a cancel command, key **38** is connected to the CPU **52** differently than the other keys. Key **38** is connected directly to the CPU **52** via an interrupt line **79**; when a keystroke is detected, a non-maskable interrupt interface (NMI) **78** (which essentially constitutes a RS422 transmitter and receiver which converts the signal on lines **75B** and **76B** to a clean logic signal on line **79**) sets an interrupt on line **79**, which is immediately detected and subsequently serviced by CPU **52**.

A similar interface is used for the remote handswitch. The cable **81** leading from the handswitch connects to the handswitch interface circuit **80** which among other things, electrically isolates the handswitch from the powerpack ground, and "de-bounces" the handswitch (eliminates electrical noise created when the switch is pressed or released) so as to provide a clean logic signal indicating whether the handswitch button is being pressed or is released. This logic signal is connected, via line **82**, to a time processor unit (TPU) port on CPU **52**. CPU **52** reads the logic signal at this TPU port and responds appropriately according to the software in EPROM **58**.

The last component on the CPU data bus **56** is an analog to digital converter (AID) **84**. This converter is used to generate a digital signal, readable through data bus **56**, which corresponds to an analog signal received on line **85**. A suitable A/D converter is the LT1094, sold by Linear Technology of 1630 McCarthy Blvd., Milpitas, Calif. 95035. A/D converter **84** is used by the motor servo control circuitry described below. The CPU has two additional interfaces to the motor servo control circuitry: an interface on line **87** to a digital to analog converter (D/A) **86** (which generates an analog signal on line **88** corresponding to a digital signal received on line **87**, for example the AD7245, sold by Analog Devices of One Technology Way, P.O. Box 9106, Norwood, Mass. 02062), and a second interface on line **90** to pressure limit control circuit **92**. These interfaces (lines **87** and **90**) connect to synchronous peripheral interface (SPI) channels on the microprocessor, and are controlled in accordance with the software in EPROM **58**.

The D/A **86**, A/D **84**, servo control **94**, pressure limit control **92**, and pressure sense **96** circuits collectively form a motor servo control circuit which controls the operation of the motor **98** which drives the syringe plunger into and out of the syringe. (Motor **98** is shown for clarity, but it should be understood that motor **98** is physically located in the powerhead **40** (FIG. **23**, **5**); lines **91** and **93** connect to the motor through several conductors of the computer interface cable connecting the powerhead **40** and the powerpack.)

Servo control circuit **94** responds to an analog voltage produced by D/A **86** on line **88** and produces a corresponding voltage between lines **99** and **100**. The voltage on lines **99** and **100** is transformed by transformer **102** to a level sufficient to drive motor **98** via lines **91** and **93**. Servo control circuit **94** contains a flyback transformer circuit which produces an output voltage related to the duty cycle of a switching FET. This duty cycle is produced by a UC3525 pulse width modulation (PWM) circuit—an integrated circuit which produces a 100 kHz digital output signal having a duty cycle which varies from 0% to 50% in response to an analog input voltage on line **88**. A suitable PWM circuit is the UC3525, sold by Unitrode of 7 Continental Boulevard, Merrimack, N.H. 03054. Thus, CPU **52** controls the speed and power output of motor **98** by writing a digital word representing a desired output voltage to D/A **86** via lines **87**; this digital word is then converted to an analog signal, and the analog signal is converted to a pulse width modulated control signal in the servo control, resulting in the desired output voltage at the motor.

Pressure sense circuit **96** includes a current sense circuit of which detects the current flow through line **93** (i.e., through the motor) and produces analog signals on lines **104** and **85** proportional to the detected current. In essence, this current sense circuit comprises a low-value, high power rating resistor in series with line **93** which attached to the motor **98**. A differential voltage amplifier (based on a low-noise, high common mode rejection op-amp) senses the voltage across the resistor and converts it to an analog voltage on lines **85** and **104**. The current flow through the motor is proportional to the force exerted by the motor and therefore to the injection pressure. Thus, the analog signals produced by pressure sense circuit **96** can be used to derive the injection pressure.

Pressure limit control circuit **92** uses the analog signal on line **104** to perform a hardware pressure control function. Pressure limit control circuit **92** contains a commercially available digital potentiometer, used to produce an analog comparison voltage. A suitable potentiometer is the DS1267, sold by Dallas Semiconductor of 4350 Beltwood Parkway South, Dallas, Tex. 75244. CPU **52** (via lines **90**) programs this potentiometer to produce a comparison voltage corresponding to the maximum allowable pressure. Pressure limit control circuit **92** includes a comparator which compares the analog signal on line **104** produced by pressure sense circuit **96** to the comparison voltage. If the pressure exceeds the maximum allowable pressure (indicating a failure in the CPU **52**), a digital signal is transmitted on line **105** to servo control circuit **94**, which in response ignores the analog signal on line **88**, and instead reduces the voltage on lines **99** and **100** to halt the motor. Thus, once the CPU **52** has programmed pressure limit control circuit **92** with the correct maximum pressure, the injector will not exceed this pressure even if the CPU **52** fails.

Under normal conditions, this hardware pressure limit will not be activated, because CPU **52** continuously obtains feedback on the performance of the motor and the pressure produced and controls the motor through D/A **86** to achieve the desired injection protocol. CPU **52** obtains feedback on an ongoing injection from three sources: (1) feedback on the injection pressure is obtained from A/D **84**, which produces a digital word on bus **56** corresponding to the analog voltage on line **85** produced by pressure sense circuit **96**; (2) feedback on the motor speed is obtained from an optical encoder **166** physically coupled to the motor inside of the powerhead **40** (elaborated with reference to FIG. **5**, below); and (3) feedback on the position of the plunger inside of the syringe is obtained from a linear potentiometer **168** physically coupled to the plunger (see FIG. **5**, below). Using this information, CPU **52** carefully controls the injection pressure, volume and speed according to a preprogrammed protocol under control of software in EPROM **58**.

Power for the powerpack, powerhead, and console display is supplied by the AC power lines **107** and **108**. The AC line voltage is conditioned by a conventional power supply circuit **106** which includes a transformer which can be adjusted for use with non-United States line voltages, and a voltage sense circuit for selecting the appropriate transformer based on the detected line voltage. The power may be turned off by unplugging the injector, or preferably by a toggle switch which opens and closes a solid-state relay in remote on/off circuit **110**.

Referring to FIG. **4**, the console circuitry is also built around a general purpose CPU **120**. A suitable microprocessor is the MC68332FN. The address bus **122** and data bus **124** connected to CPU **120** connect to a number of supporting circuits. Program ROM **126** contains the software which directs CPU **120**. (This software is written in assembly language, and is included in the attached appendix). Font ROM **128** includes font information retrieved by CPU **120** in producing fonts for text generated on the display screen. These fonts include foreign-language characters where necessary to support foreign language text. RAN **130** is used by microprocessor in performing display and retrieval operations. Battery-backed RAM **132** stores the current time of day, so that the powerpack may make a date and time-stamped record of an injection.

The primary function of the console circuitry is to generate screens on the display **32**, and to receive keystrokes from the eight-key keypad **34** (FIG. **2A**) and relay the keystrokes to the powerpack. Displays are generated by a display controller **134**, such as the F82C455 VGA contrdler sold by Chips & Technologies of 3050 Zanker Road, San Jose, Calif. 95134. This VGA controller interacts with CPU **120** via an address buffer **136** and data buffer **138**, and stores screen information in a dynamic random access memory (DRAM) **140**. Information is sent over lines **142** to the display **32**.

Keystrokes from the keypad are received by keyboard interface circuit **144** which "debounces" the keystrokes, producing clean logic signals on lines **146**. These logic signals are fed back to CPU **120** so that it may confirm keystrokes by producing an audible tone through speaker control circuit **150**. Speaker control circuit also generates unique audible signals to indicate other operations, such as the initiation of an injection, or to notify the operator that scanning should begin. A suitable controller is the MC3487, sold by Motorola.

CPU **120** communicates with the powerpack via an RS422 interface circuit **148** which sends and receives digital signals over lines **75** and **76**. Interface circuit **148** also receives and forwards keystrokes directly from keyboard interface **144**. The eight keys on the console form a single, eight bit byte of information (where each bit indicates whether the key is pressed or released). This byte is coupled directly to CPU **120** via a "245" type logical buffer.

+28 Volt DC power is received from the power supplies in the powerpack via lines **152**. A power supply circuit **154** regulates this +28 Volt DC power line into a collection of supply voltages, as needed by the various circuitry in the console. Furthermore, a power inverter circuit converts +12 Volt DC power produced by the power supply circuit **154** into low-current 600 Volt AC power supplies for energizing the liquid crystal display.

Referring to FIG. **5**, the powerhead also includes a circuit board **160** including microprocessor to perform communications with the powerpack **50** (FIG. **2C**). A suitable microprocessor is the 68HC11E2, sold by Motorola, which is a low-cost, minimal functionality microprocessor in the 68000 family. The circuit board receives and forwards keystrokes from the buttons on the keyboard **162** (described above), and electrical pulses indicating movements from the manual knob **163** mounted on the rear of the powerhead. A suitable manual knob is the model 600 thumbwheel, sold by Clarostat of 1 Washington Street, Dover, N.H. 03820. The circuit board also lights and extinguishes the injecting/fault indicator light **49A** and the enabled indicator light **49B**.

The motor **98** is coupled to a gear box which translates rotary motion of the motor to linear translation of the plunger. One suitable motor is the CYMS A2774-2 motor, sold by Barber-Colman, P.O. Box 7040, Rockford, Ill. 61125. The rotation of the motor is detected by optical encoder **166** (encoder **166** essentially comprises a pinwheel which rotates between a light source and a light detector to produce electrical pulses, for example the HEDS-9100 encoder, sold by Hewlett-Packard of 3003 Scott Boulevard, Santa Clara, Calif. 95054). Encoder **166** sends electrical pulses to circuit board **160**, which relays them to powerpack **50**, allowing CPU **52** on the powerpack to monitor movement of the motor.

The position of the plunger is detected by a linear potentiometer **168**, for example the LCPL200, sold by ETI Systems of 215 Via Del Norte, Oceanside, Calif. 92054. The wiper **169** of potentiometer **168** is mechanically coupled to and moves with the plunger **12**. A DC voltage drop is placed across the potentiometer terminals **170** and **171**, and as a result, an analog voltage representative of the location of the

plunger and wiper **169** is produced at the wiper **169**. An A/D converter on circuit board **160** converts this analog voltage to a digital signal which circuit board **160** forwards to the powerpack **50**.

Circuit board **160** also detects the output of two Hall effect sensors **172** and **174**. The powerhead has a removable face plate **42** (FIG. 2B). There are currently two different face plates having differently-sized apertures for accepting differently-sized syringes. Thus, although the face plate need not be removed to replace the syringe, it may be removed to use a different syringe size. Sensor **172** detects whether face plate **42** is open, and if so circuit board **160** sends a message to powerpack **50** which prevents any further injection procedures until the face plate is closed. Sensor **174** detects the size of the face plate in use. Currently, only one of the two face plates includes a magnet which triggers sensor **174**; thus, circuit board can determine which face plate has been installed by determining whether sensor **174** has been triggered. This information is also forwarded to CPU **52** in the powerpack so that CPU **52** may compensate for the different syringe sizes when controlling motor **98** (as described below).

At the direction of CPU **52**, circuit board **160** also controls heater blanket **176**, which heats the contrast fluid in the syringe. Furthermore, circuit board **160** controls movement indicator board **178**. Movement indicator board **178** is mechanically coupled to the plunger **12** and includes two light emitting diodes LEDs **179** which are visible through window **44** on the powerhead (FIG. 2B). LEDs **179** provide the operator with feedback on the position of the plunger, by correlating the position of the diodes with the graduated scale on window **41**. The two sides of the window **41** contain different graduated scales: one calibrated for large syringes and one for small syringes. Depending on the syringe size detected by sensor **174**, the LED next to the appropriate graduated scale is illuminated. Furthermore, as discussed in more detail below, when the plunger is moving, CPU **52** directs circuit board **160** to flash the LED. Also, when the CPU **52** enters its "locked mode" (discussed above), CPU **52** directs circuit board **160** to steadily light the LED. Thus, LEDs **179** provide operator feedback on the plunger position, direction of motion, and the "locked mode".

Referring to FIGS. 6A–6F, an injection protocol will be described from the operator's perspective. The main operating screen is illustrated in FIG. 6A. Box **200**, which is associated with an iconic representation **201** of the powerhead, identifies the current volume of contrast media in the syringe. Box **202**, which is associated with an iconic representation **203** of the syringe, identifies the total volume which has been dispensed during the currently selected protocol. Box **204** identifies the pressure limit pre-selected by the operator for the procedure, and box **206** identifies a scan delay (in seconds), which is the delay from the time the operator initiates an injection (either with the handswitch, a key on the console or a button on the powerhead) until the x ray or magnetic scan of the subject should begin (at the end of this delay, CPU **120** produces a tone indicating to the operator that scanning should begin; alternatively, scanning could be automatically initiated by a suitable electrical connection between the scanner and injector). In the illustrated situation, the syringe contains 180 ml of fluid, 30 ml of which will be used by the currently selected protocol, the pressure limit is 200 psi and there is no scan delay.

In the display illustrated in FIG. 6A, the upper regions of the screen display stored injection protocols. Region **208** identifies protocols which the operator may select, and region **210** gives details of the currently selected protocol. As shown in region **210**, a protocol comprises a number of phases; during each phase the injector produces a pre-programmed flow rate to output a pre-programmed total fluid volume. The illustrated protocol "SERIO VASCUL" has only one phase; however, other protocols which can be selected by the operator have multiple phases. In region **208**, protocols are identified by name and by number of phases; thus, as illustrated, the "LIVER" protocol has 2 phases and the "ABDOMEN PI" protocol has 3 phases.

The user can select protocols, enable an injection, and otherwise navigate through display screens by pressing the buttons on the keypad **34** next to the display. Region **212** of the display is dedicated to identifying the functions available from the buttons on the keypad **34**. Thus, in this display illustrated in FIG. 6A, the user may select the previous or next protocol in the list in region **208** by pressing the buttons next to the words "PREVIOUS PROTOCOL" and "NEXT PROTOCOL", respectively, on the display. The user may also change and store the flow, volume and inject delay values for the current protocol by pressing the button next to "CHANGE VALUES"; doing so will alter the function of the keypad and region **212** of the display, so that the operator may select a value, increment and decrement the value, select characters to form or edit a protocol name, and then return to the display shown in FIG. 6A. From FIG. 6A, the operator may also enter a control panel display (see FIG. 6E, below) to adjust operating parameters and other data. Also, the operator may enter a protocol manager in which the operator may rename or delete protocols, and may determine the order of the protocol list shown in region **208**. Finally, the user may also enable an injection from the display illustrated in FIG. 6A by pressing the button next to "ENABLE".

As shown in FIG. 6B, when the user enables an injection, as a safety measure, the injector first presents a text box **214** which asks the operator whether all of the air has been evacuated from the syringe. Region **212** of the display contains only the words "YES" and "NO", indicating that the operator must answer the question as either yes or no. If the button next to "NO" is pressed, the injection will be cancelled. If the answer is "YES", the injector will proceed to an enabled state, illustrated in FIG. 6C. Here, region **208** of the display indicates the expected duration, and region **212** includes the word "START", "AUTO ENABLE" and "EXIT". If the operator presses the button next to "EXIT", the injector will return to the state illustrated by FIG. 6A. If the operator presses the button next to "AUTO ENABLE", the injector will toggle into and out of the auto-enabled mode, as confirmed by a briefly-displayed box in the center of the screen. If the operator presses the button next to "START" the injection will begin and the injector will move to the state illustrated by FIG. 6D.

While an injection is proceeding, the display shown in FIG. 6D is displayed. In this display, region **208** indicates the total injection time and the volume (in ml) delivered to the patient. Region **212** shows the word "STOP" next to each of the buttons on the keypad **34**, indicating that the operator may stop the injection by pressing any of the buttons (or by pressing the start/stop button **45** on the powerhead, or by pressing the handswitch). In addition, in box **200**, the total volume of fluid in the syringe counts down as fluid in injected into the subject.

After the injection protocol has completed, the injector will return either to the state illustrated by FIG. 6A or to the state illustrated by FIG. 6C. If the operator put the injector in the auto-enable mode by pressing "AUTO ENABLE" at FIG. 6C, the injector will return to the state illustrated by

FIG. 6C. However, if the operator did not put the injector into the auto-enable mode, the injector will return to the state illustrated by FIG. 6A. Thus, by placing the injector in auto-enable mode, the operator can more easily repeat an injection protocol; this can be useful where, for example, the contrast media dissipates relatively rapidly, and multiple images will be taken on the same area of the subject. By using "AUTO ENABLE", the operator may replenish the contrast media just before each image by pressing a single key (or the handswitch), without re-enabling the injector.

As noted above, injection operators may wish to use prefilled syringes for injections. However, prefilled syringes often include extenders which reduce the filled volume of the syringe (syringes of this type are known as "partial pre-filled" syringes). The injector described herein includes a feature for compensating for the reduced volume of partial pre-filled syringes, described below.

As noted above, to set up the injector, the operator may enter the "Control Panel", illustrated in FIG. 6E. In the control panel, the display identifies the current operational settings of the injector. Thus, the control panel includes a box **220** which identifies the current pressure limit, a box **222** which identifies the current language (as noted above, the operator may choose a language for the textual portions of the display), boxes **226** and **228** which identify the current time and date, and a box **230** which identifies the owners registration name and/or number. This information is entered using the keypad and region **212** of the display in the manner discussed above.

An additional box **232** on the "Control Panel" display is used to indicate whether partial pre-filled syringes will be used with the injector. Box **232** will include the word "YES" or "No", as selected by the operator (as shown in FIG. 6E, when the user attempts to modify this box, region **212** of the display provides a menu with the choices "YES" or "NO").

If the operator has modified box **232** to indicate that partial pre-filled may be used (i.e., box **232** has a "YES"), then the enable procedure described above is modified slightly. If partial pre-filleds may be used, after the operator enables an injection by pressing "ENABLE" at the display of FIG. 6A, the injector presents the screen illustrated in FIG. 6F, in which the operator must identify the pre-filled syringe size by pressing a button next to "50 ml", "65 ml", "75 ml", "100 ml", or "125 ml". Once the operator has identified the prefilled syringe size, the injector will continue to the display illustrated in FIG. 6B. CPU **52** (FIG. 3) will then compensate for the extender in the syringe, in the manner described below with reference to FIG. 7B.

Referring to FIG. 7A, the program operating in CPU **52** is initiated **240** when the power is turned on. The program first initializes **242** the hardware and software attached in powerpack **50**, powerhead **40** and display **30**. Then, CPU **52** performs **244** diagnostics to ensure that the injector is operating properly; essentially, this involves sending test data to various hardware elements and verifying that the appropriate responses are received.

After these diagnostics have passed, CPU **52** initiates a number of "threads", or parallel processes; thereafter, these processes are time-multiplexed on CPU **52** under control of the above-described USX68K operating system. These threads communicate with the operating system and with each other by "messages" or semaphores—essentially, inter-process communications are placed in a globally accessible area, managed by the operating system, where they can be later retrieved by other threads. The operating system allocates processing time to the threads. Much of the time, a thread will be "inactive", i.e., it will not have any pending operations to perform. The threads are generally written so that, if the thread is inactive, it will notify the operating system of this fact ("return time" to the operating system) so that the operating system can reallocate processing time to another thread.

The operating system allocates processing time to threads in a prioritized, round-robin fashion. Thus, the operating system will provide processing time to each thread generally in turn; if an active, low-priority thread uses more than a maximum amount of processing time, the operating system will interrupt the thread, and provide other, higher priority threads with an opportunity to use processing time. However, a high-priority thread will not be interrupted by lower priority threads, regardless of whether the high-priority thread uses more than the maximum amount of processing time. Under normal operation, most of the threads are inactive, and there is no conflict between threads for processing time; however, in those occasions where there is a conflict, this prioritized system allows the most important threads to continue uninterrupted where necessary. It should be noted, however, that even the highest priority thread (servo thread **254**) occasionally returns time to the operating system (at those moments where an interruption can be tolerated), so that other threads are able to continue their operations even while the highest priority thread is active.

The threads operating in the CPU **52** generally fall into two categories: "communicating" threads which send information into and out of the powerpack **50**, and "operating" threads which generate or process the information sent or received by the powerpack. There are two operating threads: state machine thread **246** and servo thread **254**.

State machine thread **246** directs the console **30** to produce screen displays of the type shown in FIGS. 6A–6E, and also processes button presses by the user. Thread **246** is essentially a state machine, where each "state" corresponds to a display screen, and each operator keystroke produces a state transition. The software in program EPROM **58** (FIG. 3) essentially defines a state transition diagram, identifying specific states, displays associated with those states, and, for each state, the keystrokes or other activity which will cause a transition to another state.

As shown in FIG. 7B, when initiated, thread **246** looks **270** for a message, for example a message from a communications thread indicating that console button was pressed, or a message from the servo thread indicating that the display should be updated to reflect recent injection activity. If no message has been received, the thread returns **272** time to the operating system. However, if a message has been received, the thread uses the software in program EPROM **58** to identify and transition **274** to the new state associated with the received keystroke or activity. In some cases, e.g. where the operator has pressed an invalid button, the new state will be the same as the old state; in other cases, the new state will be a different state. If the new state is a different state, the state machine thread sends messages to the appropriate communication thread to modify **276** the screen to reflect the new state. In addition, the state machine thread may send 278 messages to the servo thread, e.g. to notify the servo thread that the operator has pressed a button which starts a protocol. When this is completed, the state machine returns 280 to the operating system.

When a start message is sent to the servo thread, the thread sending the message initiates one or more global variables to indicate the kind of movement requested. Eight

global variables (variables managed by the operating system and accessible by all threads), organized into four pairs, are used for this purpose. Each pair of variables identifies a desired new position for the plunger and a speed at which the plunger should move to that position. Four protocol phases can be described by the four variable pairs, and thus may be executed in one message to the servo thread. Thus, when the state machine thread sends **278** a message to the servo thread, it computes one or more desired ending positions and speeds from the selected protocol, and places the computed values into global variables.

Referring to FIG. **7**C, when initiated by the operating system, the servo thread **254** first checks **282** for a message telling the servo to start motion of the plunger. If no message is received, the servo thread returns **284** time to the operating system. If, however, a start message has been received, the servo thread starts **286** the motor to move to the desired position indicated by a global variable at the desired speed indicated by a global variable. At this point, the servo thread enters a loop; during each iteration the loop checks **288** if the plunger has arrived at the desired position (the plunger position is determined by the powerhead receive thread **260** as illustrated in FIG. **7**E, below), and if so, the loop terminates and the servo thread stops **290** the motor and returns. However, if the plunger has not arrived at the desired position, the servo thread checks **292** if the speed of the motor is correct (the motor speed is measured by an interrupt routine illustrated in FIG. **7**D, below). If the motor speed is incorrect, it is corrected **294** by adjusting the motor voltage. Once these steps are completed, the servo thread allows **296** the operating system three time slices (about 21 milliseconds) to operate other processes, after which it returns to step **288** to close the loop.

Referring to FIG. **7**D, as noted above, the motor speed is measured by an interrupt routine. When a pulse is detected from the optical encoder **166** (FIG. **5**) attached to the motor **98**, the processor in the powerhead circuit board **160** causes an interrupt to travel on line **71** to CPU **52**. When this interrupt is received **300**, the interrupt routine computes **302** the time elapsed from the previous count interrupt, and from this elapsed time computes **304** the plunger speed. This speed value is stored **306** in a global variable (where it can be accessed by the servo routine), and the interrupt is done **308**.

Referring to FIG. **7**E, the powerhead receive thread **260** is responsible for receiving messages from the powerhead and performing a number of tasks in response, including relaying manual movements of the plunger to the servo thread and (as noted above) relaying position measurements to the servo thread during movement of the plunger.

When the operating system initiates **260** the powerhead thread, the thread first checks **310** for any messages; if none have been received, the thread returns **312** time to the operating system. However, if the thread has received a message, it determines **312** what the message is and acts appropriately (this determination is illustrated for clarity as a multi-way branch, but in the code in the fiche appendix it is implemented as a series of individual tests performed on in sequence). The message may contain an error message **314**, a manual knob movement **316**, a linear potentiometer reading **318** (which are periodically generated by the powerhead), a fill button reading **320** (which is periodically generated by the powerhead), a start/stop button press **322**, or several others (multiple messages may be received at one time).

As shown in FIG. **7**E, if the message contains a linear potentiometer reading **318**, the reading is converted **324** into an equivalent volume (using calibration readings stored in EEPROM **62**). Then, an offset value (which compensates for the presence of the extender in a partial pre-filled syringe), is subtracted **326** from the computed volume, and the result is stored in a global variable, where it can be later accessed by the servo thread at step **288** (FIG. **7**C). The offset value used in step **326** is generated when the user identifies the partial pre-filled size in response to the display shown in FIG. **6**F; if partial pre-filled syringes are not used, the offset is set to a constant zero value. Once the adjusted volume is stored, the powerhead thread returns **328** time to the operating system.

As shown in FIG. **7**F, when a fill button reading is received (i.e., the received message indicates the state of buttons **46**, **47** and **48** on the keyboard **162** of the powerhead), the powerhead thread first determines **330** which button, or buttons, are pressed.

If a "fast" button **48** and the forward button **46** or reverse button **47** are pressed **332**, the thread first determines **334** whether the motor is at its maximum, latching speed (by reading the global variable indicating the motor speed, as produced by the interrupt routine illustrated in FIG. **7**D). If not, the thread increases **336** the motor speed in the indicated direction—by increasing the value of the global variable identifying the desired speed, setting the global variable identifying the desired location to identify the end of the syringe (and sending a start servo message to the servo thread if the motor is not already running)—and returns **338** time to the operating system. If, however, the motor has reached its latching speed, then the thread determines **340** if buttons were pressed the last time a fill button reading was processed. If so, then the operator has accelerated the motor to its maximum speed and is continuing to hold down the buttons. In this situation, the motor should continue running at its maximum speed; therefore, the thread simply returns **338** time to the operating system. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If the operator is pressing **344** the forward or reverse buttons alone, or any other combination of buttons, the thread first determines **346** if the motor is running (by checking the value of the global variable indicating the motor speed). If the motor not running, then a single keystroke will not start it running, so the thread simply returns **338** to the operating system. If, however, the motor is running, then the thread determines **348** if buttons were pressed the last time a fill button reading was processed. If buttons were pressed last time, then the operator is merely trying to keep the motor running at its current speed by holding a button down; therefore, in this situation, the thread simply returns **338** to the operating system, allowing the motor to continue running. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If no buttons are pressed **352**, the thread simply determines **354** if the motor is at its latching speed. If not, the thread stops **356** the motor and returns time to the operating system. Otherwise, the thread returns **338** directly, allowing the motor to continue running at the latching speed.

Referring to FIG. 7G, manual motion can also be created by turning the manual knob **163** (FIG. **5**) mounted on the rear of the powerhead. As noted above, the powerhead CPU **160** regularly reports movements of the manual knob to the powerpack CPU **52**. This report identifies the direction of rotation and the number of electrical pulses received from the knob since the last report (more pulses indicating greater speed of rotation). When a manual knob message is received **316**, the powerhead receive thread first computes **340** a desired plunger speed from the number of pulses identified in the message, and computes **342** a desired end position from the number of pulses and the direction of rotation of the knob. These are then stored **344** in global variables accessible to the servo thread as described above. If the motor is not already running, the powerhead receive thread also sends a servo start message to the servo thread. Then the thread returns **346** time to the operating system.

The invention has been described with reference to a specific embodiment. However, it will now be understood that various modifications and alterations can be made to this specific embodiment without departing from the inventive concepts embodied therein. For example, the manual motion knob **163** may be replaced by any other control which allows velocity and direction control, for example by a button or knob which can be rotated or rocked to multiple positions corresponding to various velocities and directions of motions, or a set of buttons or knobs which allow the operator to separately select a desired velocity with one button or knob and a desired direction with another button or knob. Therefore, this specific embodiment is to be interpreted as exemplary and not limiting, with the scope of protection being determined solely from the following claims.

What is claimed is:

1. An injector and syringe, comprising:

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector,

a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

2. The injector of claim **1** wherein said control circuit ceases motion of said motor and plunger when a location of said plunger computed by said control circuit indicates that said plunger has arrived at an end of said syringe.

3. The injector of claim **1** wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

4. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

5. The method of claim **4** further comprising:

ceasing motion of said plunger when a computed location of said plunger indicates that said plunger has arrived at an end of said syringe.

6. The method of claim **4** wherein said electrical signal represents the length of an extender which is attached to said plunger.

7. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the amount of fluid in the syringe,

a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the amount of fluid in said syringe using said electrical signal and the tracked location of said motor.

8. The injector of claim **7** wherein said control circuit ceases motion of said motor and plunger when a location of said plunger computed by said control circuit indicates that said syringe is empty.

9. The injector of claim **7** wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

10. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to amount of fluid in said syringe, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the amount of fluid in said syringe using said electrical signal and the tracked location of said motor.

11. The method of claim **10** further comprising:

ceasing motion of said plunger when a computed location of said plunger indicates that said syringe is empty.

12. The method of claim 10 wherein said electrical signal represents the length of an extender which is attached to said plunger.

13. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector,

a motor in the injector which advances and retracts a ram coupled to the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit determines that the ram hag arrived at its end of travel position, using said electrical signal and the tracked location of said motor.

14. The injector of claim 13 wherein said control circuit ceases motion of said motor and plunger when the ram has reached its end of travel position.

15. The injector of claim 13 wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

16. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the end of travel position of a ram moved by said motor when said syringe is mounted to the injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

determining that a ram moved by said motor has arrived at its end of travel position, using said electrical signal and the tracked location of said motor.

17. The method of claim 16 further comprising:

ceasing motion of said plunger when said ram reaches its end of travel position.

18. The method of claim 16 wherein said electrical signal represents the length of an extender which is attached to said plunger.

19. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector,

a motor in the injector which advances and retracts a ram coupled to the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the range of travel of said ram moved by said motor, using said electrical signal.

20. The injector of claim 19 wherein said control circuit ceases motion of said motor and plunger when the ram has reached and end of its computed range of travel.

21. The injector of claim 19 wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

22. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the range of travel of a ram moved by said motor when said syringe is mounted to the injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the range of travel of a ram moved by said motor, using said electrical signal and the tracked location of said motor.

23. The method of claim 22 further comprising:

ceasing motion of said plunger when said ram reaches and end of its range of travel.

24. The method of claim 22 wherein said electrical signal represents the length of an extender which is attached to said plunger.

25. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of the syringe, and physical indicia,

a motor which advances and retracts the plunger within the syringe toward and away from the nozzle to inject fluid into or out of an animal subject, and

a controller comprising

a control circuit which causes the motor to move and tracks the location of the motor while moving the motor, and

a memory storing an offset value which is related to the capacity of said syringe,

wherein the control circuit is operable obtain an offset value from physical indicia detected on the syringe, and the control circuit computes a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and ceases motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

26. The injector of claim 25 wherein said offset value represents the length of an extender which is attached to said plunger within said syringe.

27. A method of controlling an injector of the type having a motor which advances and retracts a plunger within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, comprising

causing the motor to move and tracking the location of the motor while moving the motor,

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of said syringe, to obtain an offset value,

computing a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and

ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

28. The method of claim 27 wherein said offset value represents the length of an extender which is attached to said plunger within said syringe.

* * * * *

No. 04-32

IN THE

Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit properly applied well-settled principles of patent law governing claim construction to the patents in suit.

DISCLOSURE STATEMENT

Respondent Liebel-Flarsheim Co. is a wholly-owred subsidiary of Mallinckrodt Inc. Mallinckrodt Inc. is in turn a wholly-owned subsidiary of Tyco International, Ltd. a publicly traded company. No publicly-held company owns 10% or more of the stock of Tyco International, Ltd.

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TABLE OF CITED AUTHORITIES

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Cases:

Abbott Labs. v. Baxter Pharmaceutical Products, Inc., 334 F.3d 1274 (Fed. Cir. 2003) 15

Acromed Corp. v. Sofamor Danek Group, Inc., 253 F.3d 1371 (Fed. Cir. 2001) 16

Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp., 294 U.S. 477 (1935) 13

Anchor Wall Systems v. Rockwood Retaining Walls, Inc., 340 F.3d 1298 (Fed. Cir. 2003) 15

Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961) 13

Bayer AG v. Biovail Corp., 279 F.3d 1340 (Fed. Cir. 2002) 16

Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294 (Fed. Cir. 2003) 7

Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334 (Fed. Cir. 1999) 16

Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182 (Fed. Cir. 1998) 8, 17

Cited Authorities

Page

Continental Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405 (1908) 13, 14

Electro Med. Sys. v. Cooper Life Sciences, Inc., 34 F.3d 1048 (Fed. Cir. 1994) 17

Elster Electricity LLC v. Schlumbergersema Inc., 2004 U.S. App. LEXIS 15796 (Fed. Cir. July 30, 2004) 23

Glaxo Group Ltd. v. Apotex, Inc., 2004 U.S. App. LEXIS 15489 (Fed. Cir. July 27, 2004) 23

Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327 (Fed. Cir. 2004) 15

Housey Pharmaceuticals, Inc. v. Astrazeneca UK, Ltd., 366 F.3d 1348 (Fed. Cir. 2004) 11

Innova/Pure Water, Inc. v. Safari WaterFiltration Systems, Inc., 2004 U.S. App. LEXIS 16549 (Fed. Cir. August 11, 2004) 14, 23

Intel Corp. v. U. S. Int'l Trade Comm'n, 946 F.2d 821 (Fed. Cir. 1991) 17

Intervet America, Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050 (Fed. Cir. 1989) 17

Cited Authorities

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Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985 (Fed. Cir. 1999)	16
Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968 (Fed. Cir. 1999)	16
Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352 (Fed. Cir. 2000)	16
Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855 (Fed. Cir. 1988)	17
Laitram Corp. v. NEC Corp., 163 F.3d 1342 (Fed. Cir. 1998)	17
Linear Tech. Corp. v. Impala Linear Corp., 371 F.3d 1364 (Fed. Cir. 2004)	11
Mars, Inc. v. H.J. Heinz Co., 2004 U.S. App. LEXIS 15640 (Fed. Cir. July 29, 2004)	23
McCarty v. Lehigh Valley R.R. Co., 160 U.S. 110 (1895)	14
Merrill v. Yeomans, 94 U.S. 568 (1876)	13
Microsoft Corp. v. Multi-Systems, Inc., 357 F.3d 1340 (Fed. Cir. 2004)	19
Neomagic Corp. v. Trident Microsystems, Inc., U.S. App. LEXIS 16178 (Fed. Cir. August 5, 2004)	23

Cited Authorities

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Northrop Grumman Corp. v. Intel Corp., 325 F.3d 1346 (Fed. Cir. 2003)	7
In re Paulsen, 30 F.3d 1475 (Fed. Cir. 1994)	17
Phillips v. AWH Corp., Federal Circuit Appeal Nos. 03-1269,-1286	21, 22, 23
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The Petition presents no general legal issue meriting review much less any controversial questions of law demanding this Court's attention. There is no division within the Federal Circuit over the well-settled principle of patent law that it is the claims of a patent that define the invention to which the patentee is entitled the right to exclude and that, even where a patent describes a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit claim scope using words or expressions of manifest exclusion or restriction. This principle fully respects the claim-based system for defining inventions in effect since 1836 and inevitably calls for a patent-specific inquiry. The Federal Circuit's application of this principle in this case was a fact-specific application of time-honored principles of claim construction to the patents in suit and was correct. Petitioner's challenge to the decision presents only case-specific issues not appropriate for review by this Court and should be denied.

COUNTER-STATEMENT OF THE CASE

I. Procedural History

Respondent Liebel-Flarsheim Co.[1] brought the present action in 1998 alleging, among other things, that Petitioner Medrad, Inc. was infringing, inducing infringement of and contributorily infringing upon four L-F patents all directed to L-F's new and unique front-loading powered medical injector and syringes and controls therefor for delivering

1. Mallinckrodt Inc., the parent of Liebel-Flarsheim Co., was added as a party on the motion of Petitioner. Liebel-Flarsheim Co. and Mallinckrodt Inc. will be referred to collectively as "L-F".

contrast agents to patients during certain medical diagnostic procedures.[2]

The district court granted Petitioner summary judgment of non-infringement with respect to all four patents by orders filed October 18, 2001 and February 19, 2002. (Pet. App. 37, 105). The Federal Circuit reversed and remanded in a decision issued on February 11, 2004, holding simply and unremarkably that, absent a clear disclaimer of particular subject matter, the mere fact that the inventor disclosed only a single embodiment of his invention in the specification was not grounds to limit the claims of the patents to that particular structure. (App. 1, 8, 19-20). Petitioner's motion for rehearing and rehearing *en banc* was denied on April 2, 2004. On April 7, 2004, Petitioner moved to stay issuance of the mandate pending filing of a petition for writ of certiorari. The Federal Circuit denied Petitioner's motion on April 13, 2004. Petitioner did not move in this Court for a stay. On issuance of the mandate and remand to the district court, Petitioner again moved for a stay. Petitioner's motion was denied by the district court.

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2. U.S. Patent No. 5,456,669 ("the '669 patent") entitled "Method of Front Loading an Injector and Injecting Fluid Into Animals Therewith", U.S. Patent No. 5,650,261 ("the '261 patent") entitled "Disposable Front Loadable Syringe", U.S. Patent No. 5,662,612 ("the '612 patent"), and U.S. Patent No. 5,920,197 ("the '197 patent") both entitled "Controlling Plunger Drives For Fluid Injections In Animals".

II. Background

L-F's patented inventions relate to a remarkable development in the field of medical diagnostic imaging equipment, specifically to front-loadable powered injectors and automatic control of the plunger driver during the injection process, for use in imaging such as in angiographic, computed tomography, magnetic resonance and ultrasound imaging procedures. Prior to L-F's inventions, powered injectors required that the syringes be inserted in the injector by a breech-load method. As the district court observed, loading of the syringes by the breech-load method was cumbersome, time-consuming, and inefficient and presented a cleanliness problem and posed a safety hazard. (Pet. App. 38).

As a result of L-F's inventive efforts in the late 1980s, L-F introduced to the marketplace the first front-loadable powered injection system. This system eliminated the disadvantages inherent in the breech-loading power medical injectors then the industry standard and provided benefits in terms of use, speed, efficiency, sterility, and cleanliness theretofore unavailable in the art. *Id.* As the Federal Circuit correctly observed, L-F's patents are directed to front loading, rather than breech loading powered injectors. (Pet. App. 3). After Petitioner introduced its version of a front loading powered medical injector, this suit was brought.

From the outset, Petitioner attempted to limit the asserted claims of the '669 and '261 patents to the particular embodiment disclosed in the specifications, which used a pressure jacket around the syringes. In an attempt to avoid a finding of infringement, Petitioner at every turn attempted to convince the district court and the Federal Circuit (and

now this Court) that a front-load powered medical injector which did not employ a pressure jacket was somehow different in kind from L-F's invention. However, Petitioner's litigation-induced position was belied by the record developed in the district court that included extensive evidence that in the design process the L-F inventors considered front-loading injector designs with and without a pressure jacket, that Petitioner itself viewed a pressure jacket version and a version without a pressure jacket throughout its development simply as "design alternatives" and that Petitioner believed then and now that the concept of a front loading powered medical injector, regardless of whether it used a pressure jacket, was a patentable invention.[3]

In addition, Petitioner filed its own later patent application which issued as U.S. Patent No. 5,383,858 ("the '858 patent"). (Opp. App. 1). In that application, Petitioner described two design alternatives. One was a front loading powered injector without a pressure jacket and one was a front loading powered injector with a pressure jacket. Figs. 1-

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3. Indeed, when Petitioner first introduced its version of a front loadable injector, it touted the advantages of front loading in its sales literature without any reference to a prèssure jacket:

> **NEW! Front Load Capability**
>
> One step syringe engagement
>
> One step disposal of the syringe and tubing . . . together as a unit . . . no need to disconnect tubing . . .
>
> . . .it's just that easy . . . no mess to clean up.
>
> **A *Quarter Turn* for One-Hand Operation**

(Opp. App. 14-15).

8; col. 3, l. 64 - col. 7, l. 36 and Figs. 9-10; col. 7, l. 37 - col. 8, l.51, respectively. Petitioner stated that the pressure jacket could be eliminated simply by making the syringe stronger, e.g., by using a relatively strong plastic or by providing the syringe with annular reinforcing ribs. ('858 patent at col. 9, l. 24-27) (Opp. App. 11).

With respect to the '612 and '197 patents, Petitioner sought to limit the asserted claims to a control system that sensed only the presence of an extender on a prefilled syringe.

In spite of over 100 years of this Court's precedent and numerous Federal Circuit decisions, the district court read into the asserted claims of the '669 and '261 patents a requirement for a pressure jacket because that was what was illustrated in the specification as the preferred embodiment. Contrary to Petitioner's statement of the case (Pet. 6), the district court did not reject any dictionary definition of the word "opening." To the contrary, the district court held that term "opening" was clear and unambiguous (Pet. App. 51-52), and neither party asserted the contrary on appeal. Rather, the district court simply violated this Court's and the Federal Circuit's oft-stated proscription on reading into patent claims limitations from the specification.

The district court rejected Petitioner's attempt to limit the scope of the asserted claims of the '612 and '197 patents finding ample evidence in the prosecution that the claims extended to a variety of syringe-related properties. (Pet. App. 72-77). But the district court then read into the asserted claims the limitation that syringe-encoded information be used *directly* in the control of the injector, a term nowhere found in either the claims or the specification and a reading of the claims proposed by neither party.

III. The Federal Circuit's Claim Construction

A. The '669 and '261 Patents

The Federal Circuit began its analysis of the '669 and '261 patents by reiterating the well-established need to respect both of two cautions: one against reading limitations appearing only in the specification into the claims that carry a plain broader meaning; the other requiring that the claims be read in view of the specification. (Pet. App. 10-11). This is a patent-intensive and case-specific inquiry. The court then recited its extensive precedent rejecting "the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." (Pet. App. 13-14). The court reiterated its *Teleflex* ruling that even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using "words or expressions of manifest exclusion or restriction." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002). (Pet. App. 14).

The court then examined several of the cases relied upon by Petitioner, specifically *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001), and *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999), and carefully pointed out the distinctions between the patents and prosecution histories in those cases. (Pet. App. 14-16). The court then cited a number of its other decisions noting that "[i]n each of those cases, however, there were specific reasons dictating a narrow claim construction beyond the

mere fact that the specification disclosed only a single embodiment or a particular structure." (Pet. App. 16-18).

The court then examined the common specifications for any evidence of a clear disclaimer of subject matter and, finding none, concluded that: "This case is therefore governed by the principle that '[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context.'" (Pet. App. 18-20) (citing *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1355 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003); *Teleflex*, 299 F.3d at 1328).

The court next examined the prosecution histories of the '669 and '261 patents and found that they were "squarely contrary to [Petitioner's] contention that all the claims of those two patents require injectors that use pressure jackets." (Pet. App. 20). The Federal Circuit noted that during prosecution L-F had replaced claims that had included references to a pressure jacket with new claims that did not, providing, in the words of the Federal Circuit, "a strong indication that the applicants intended those claims to reach injectors that did not use pressure jackets." The court further noted that during the prosecution of the '261 patent, L-F had specifically stated to the Examiner who allowed the claims that there was not "necessarily a pressure jacket" in the claimed devices. (Pet. App. 20-21).

Finally, the court examined the claims of the '669 and '261 patents and observed the juxtaposition of independent claims lacking any reference to any pressure jackets with dependent claims that add a pressure jacket limitation.

The court held that this provides "strong support for Liebel's argument that the independent claims do not require the presence of a pressure jacket." (Pet. App. 22) (citing *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001); *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998)). *See also Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302-03 (Fed. Cir. 2003) (the presumption that an independent claim does not have the limitation that is introduced for the first time in a dependent claim "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging the limitation in the dependent claim should be read into the independent claim").

In sum, the Federal Circuit concluded that the asserted claims of the '669 and '261 patents do not expressly require pressure jackets, that Petitioner had failed to point to a clear disavowal of claim scope in either the written description or the prosecution histories and that, in fact, the prosecution histories were squarely contrary to Petitioner's argument. The court thus concluded that the district court's claim construction requiring pressure jackets was erroneous. (Pet. App. 26).

Thus, contrary to what Petitioner seems to argue, the court did not begin and end its analysis by looking at the ordinary meaning of the word "opening" but rather carefully and methodically examined all of the claims, the patent specifications and the prosecution histories. The Federal Circuit asked Petitioner to point to words of manifest exclusion of claim scope in either the patent specifications or the prosecution histories, and Petitioner was unable to do so.

B. The '621 and '197 Patents

The district court's claim construction was easily reviewed. The court noted that there was nothing in the words "related to" or "using" that required a direct as opposed to an indirect relationship. Petitioner pointed to nothing in the patent specifications that would limit the claims to a direct relationship. Petitioner pointed only to the prosecution. The Federal Circuit carefully examined Petitioner's prosecution-based argument and determined that the applicants had not disclaimed an "indirect" relationship.

Accordingly, since the plain language of the claims and prosecution history did not support a claim construction limiting the relationship between the physical indicia and the syringe properties to a direct relationship, the Federal Circuit reversed the district court's claim construction.

REASONS FOR DENYING THE PETITION

I. The Federal Circuit Has Properly Articulated The Well-Settled Principle That Absent A Clear Disclaimer Of Particular Subject Matter, Particular Embodiments Appearing In The Specification Will Not Be Read Into The Claims For The Purpose Of Limiting Their Scope.

Petitioner attempts to manufacture an issue meriting review by this Court by arguing that the law on claim construction in the Federal Circuit is "chaotic."[4] Petitioner

4. Petitioner cites articles reciting high reversal rates on claim construction in the Federal Circuit. However, a number of others, both judges and commentators, have referred to these figures as misleading and unreliable. Judge Lourie of the Federal Circuit attributes the reversal rates to several factors, including the fact that the appellate court "digs into" all of its appeals, that Federal Circuit clerks have technical backgrounds that most district court judges lack, that the Federal Circuit is a "semi-specialized" court, so "it's not surprising that we arrive at a different result from the district court." Further, he noted that papers commenting on the reversal rates fail to take into consideration unpublished opinions by the court upholding trial court claim construction rulings. In his view, patent litigation is "getting simpler," thanks to this Court's *Markman* ruling that claim construction is a matter of law for the judge, not the jury, to decide. 66 PTCJ No. 1639 at 580 (Sept. 26. 2003).

The article cited by petitioner for its statistic of a 74% reversal rate (29 out of 39 cases from approximately September 2002 through June 2003) itself notes that the majority of district court errors in claim construction were due to a district court's narrow claim construction, i.e., "the district courts have overlooked the ordinary and accustomed meaning of claim terms." David J. F. Gross, et al., *You Must be Mistaken: Federal Circuit 'Corrections' of District Court Claim Constructions (2002-03)*, 766 PLI/Pat at 34 (2003). The authors conclude that rather

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than adopting a cynical approach of moving cases to the Federal Circuit early, "the district court should focus on the 'plain meaning' of the terms in some fashion." The authors' "Bottom-line": "Just as patent lawyers may reasonably disagree about the meaning of claim terms, so will judges of the district courts and Federal Circuit." *Id.* at 61-62.

Wagner and Petherbridge also cited by Petitioner concluded that "a new Federal Circuit is emerging — one that appears to be more rules-driven and more consistent than before." R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. Pa. L. R. 1105, 1179 (2004).

Nor does Judge Newman's dissent in *Housey Pharmaceuticals, Inc. v. Astrazeneca UK, Ltd.*, 366 F.3d 1348 (Fed. Cir. 2004), support Petitioner's assertion of "chaos." That case involved four patents addressing methods of screening for protein inhibitors and activators. At issue were the words "inhibitor or activator of a protein." The *patentee* sought a narrow construction of the claims to save them from invalidity. The district court, however, held that the words meant "a substance that has a greater effect on the phenotype of cells that express the protein of interest at a higher level than on the phenotype of cells that express the protein of interest at a lower level or not at all." *Id.* at 1351. The Federal Circuit affirmed. In doing so, the court looked at the plain and ordinary meaning of the claim language and also the specification and the prosecution history to determine if the patentee had disclaimed or disavowed claim scope. Looking at the intrinsic evidence, the court concluded that the patent did not clearly disavow its broad plain meaning. *Id.* at 1351-1353. Judge Newman in dissent observed that "[t]he specification, on its face, can support either theory . . .", *id.* at 1359, so it is difficult to discern her complaint. The business of judging often requires making choices. Judge Newman would have reversed the district court (thus adding to the reversal statistics) and remanded for the district judge to hear conflicting expert testimony (i.e., extrinsic evidence). *Housey's* petition for rehearing *en banc* was denied on August 25, 2004.

It is well to note that Judge Newman just this June joined the panel in *Linear Tech. Corp. v. Impala Linear Corp.*, 371 F.3d 1364, 1376 (Fed. Cir. 2004), in which the plain meaning of the term "concurrently" was determined using a dictionary.

accuses the Federal Circuit of ignoring what it labels a "*Markman*-type" approach to claim construction as opposed to "ordinary meaning." Petitioner is clearly wrong because the Federal Circuit's decision in this case shows adherence to *Markman* (Pet. App. 10) and a careful analysis of the claims, patent specifications and prosecution histories (i.e., the so-called intrinsic evidence) of all four patents in suit. Petitioner is clearly wrong when it portrays this case as having been decided based on extrinsic dictionary definitions without reference to the claims, specifications and prosecution histories. Nowhere did the Federal Circuit refer to competing dictionary definitions (i.e., non-technical versus technical) in arriving at its decision. The court simply looked at the simple, clear and unambiguous words "opening", "related to" and "using" and saw no basis in the claims themselves, the specifications or prosecution histories to limit the claims in the case of the '669 and '261 patents to the preferred embodiment and in the case of the '612 and '197 patents to a "direct" relationship nowhere referred to in the intrinsic evidence. Petitioner should recall that in the Federal Circuit, it did not argue as a basis for its appeal that the district court's definition was wrong. Petitioner should also recall that when the Federal Circuit challenged it to point to a clear disavowal of claim scope in either the written description or the prosecution histories, it was unable to do so. (Pet. App. 26).

Petitioner can prevail in this case only if this Court adopts Petitioner's proposed claim construction that in all cases patent claims can have a scope no broader than the particular embodiments described in the patent specifications. Petitioner's proposed claim construction, however, flies in the face of this Court's well-settled and long-standing jurisprudence as well as that of the Federal Circuit.

It has been a bedrock principle of patent law for well over 100 years that the claims of a patent define the invention to which the patentee is entitled the right to exclude. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("[T]he claims made in the patent are the sole measure of the grant."); *Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935) ("Under the statute it is the claims of the patent which define the invention."); *Smith v. Snow*, 294 U.S. 1, 11 (1935) ("[T]he claims of the patent, not its specifications, measure the invention."); *Continental Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) ("In making his claim the inventor is at liberty to choose his own form of expression, and while the courts may construe the same in view of the specifications and the state of the art, they may not add to or detract from the claim." (citation omitted)); *White v. Dunbar*, 119 U.S. 47, 52 (1886) ("The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public . . . to construe it in a manner different from the plain import of its terms."); *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) ("[The statutorily required] distinct and formal claim is, therefore, of primary importance, in the effort to ascertain precisely what it is that is patented to the appellant in this case."). Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to "particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention." 35 U.S.C. § 112.

As Justice Bradley famously stated:

> Some persons seem to suppose that a claim in a patent is like a nose of wax which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express. The context may, undoubtedly, be resorted to, and often is resorted to, for the purpose of better understanding the meaning of the claim; but not for the purpose of changing it, and making it different from what it is. The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms. This has been so often expressed in the opinions of this court that it is unnecessary to pursue the subject further.

White, 119 U.S. at 51-52; *see also Continental Paper Bag*, 210 U.S. at 419; *McCarty v. Lehigh Valley R.R. Co.*, 160 U.S. 110, 116 (1895) ("[W]e know of no principle of law which would authorize us to read into a claim an element which is not present. . . . The difficulty is that if we once begin to include elements not mentioned in the claim . . . , we should never know where to stop.").

This principle is likewise firmly established in the Federal Circuit.[5]

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5. *Innova/Pure Water, Inc. v. Safari WaterFiltration Systems, Inc.*, 2004 U.S. App. LEXIS 16549, *15 (Fed. Cir. August 11, 2004) ("[P]articular embodiments appearing in the written description will not

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be used to limit claim language that has broader effect."); *Unitherm Food Systems, Inc. v. Jennie-O-Foods, Inc.*, App. Nos. 03-1472, -1473, 2004 U.S. Dist. App. LEXIS 14274, *24-25 (Fed. Cir. July 12, 2004) ("We have often stated that while . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."); *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1331 (Fed. Cir. 2004) ("While claims must be construed in light of the specification, limitations from the specification are not to be read into the claims, for it is the claims that measure the invention", internal quotations and citations omitted); *Taskett v. Dentlinger*, 344 F.3d 1337, 1340 (Fed. Cir. 2003) ("Though it is true that we must read a claim in light of the specification, rarely will we limit the claim to the preferred embodiments described in that specification."); *Anchor Wall Systems v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003) (concluding that including element in claim "would be to impermissibly read a limitation into the claims from the written description."); *Sunrace Roots*, 336 F.3d at 1304 ("We believe the district court erred in relying on various statements in the written description to conclude that the term shift actuator should be limited to a device containing the cam structure of the preferred embodiment."); *Abbott Labs. v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003) ("This court interprets patent claims in light of the specification, but this axiom does not mean that everything expressed in the specification must be read into all the claims. Claims are not necessarily and not usually limited in scope simply to the preferred embodiment", internal quotations and citations omitted); *RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1265 (Fed. Cir. 2003) ("[C]ourts may not use the teaching of the specification to contradict the clear language of the claims. To require the filter media of claim 1 to be multi-layered would impermissibly read limitations from the specification into the claim."); *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1149 (Fed. Cir. 2003) (concluding that to limit the claims "here would be to impermissibly read a limitation into the claims from the written description."); *Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1204
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(Fed. Cir. 2002) ("Consulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims."); *Teleflex*, 299 F.3d at 1326 ("As we have often stated, the claims must be read in view of the specification, but limitations from the specification are not to be read into the claims", internal quotations and citations omitted); *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002) ("While a court may look to the specification and prosecution history to interpret what a patentee meant by a word or phrase in a claim, extraneous limitations cannot be read into the claims from the specification or prosecution history."); *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1382 (Fed. Cir. 2001) ("This court will not limit a patent to its preferred embodiments in the face of evidence of broader coverage by the claims."); *Wenger Mfg.*, 239 F.3d at 1237 ("Although claims must be read in light of the specification of which they are a part, it is improper to read limitations from the written description into a claim."); *Tate Access Floors v. Maxcess Technologies, Inc.*, 222 F.3d 958, 966 (Fed. Cir. 2000) ("Although claims must be read in light of the specification of which they are a part, it is improper to read limitations from the written description into a claim", internal quotations and citations omitted); *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1362 (Fed. Cir. 2000) ("Specifically, we have noted the danger of reading limitations into the claims from the preferred embodiments".); *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999) ("Consistent with the principle that the patented invention is defined by the claims, we have often held that limitations cannot be read into the claims from the specification or the prosecution history."); *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 973 (Fed. Cir. 1999) ("The general rule, of course, is that the claims of a patent are not limited to the preferred embodiment, unless by their own language."); *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989-90 (Fed. Cir. 1999) ("[C]laim terms cannot be narrowed by reference to the written description or prosecution history unless the
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language of the claims invites reference to those sources."); *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998) (noting it is a "well-established principle that a court may not import limitations from the written description into the claims"); *Comark Communications*, 156 F.3d at 1186 ("[L]imitations from the specification are not to be read into the claims."); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 866 (Fed. Cir. 1997); *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) ("AST engages in a *post hoc* attempt to redefine the claimed invention by impermissibly incorporating language appearing in the specification into the claims."); *Electro Med. Sys. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994) ("[C]laims are not to be interpreted by adding limitations appearing only in the specification."); *Intel Corp. v. U. S. Int'l Trade Comm'n*, 946 F.2d 821, 836 (Fed. Cir. 1991) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims."); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."); *Intervet America, Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989)

> [T]his court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into the claims, and that interpreting what is *meant* by a word *in* a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper

Internal quotations omitted; *Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988) ("[T]he general principle is that limitations from the specification are not to be read into the claims."); *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims."); *SRI Int'l v. Matsushita Electric Corp. of Am.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) (*en banc*) ("That a specification describes only one embodiment does not require that each claim be limited to that one embodiment.").

Petitioner's Questions Presented thus presents no issues suitable for review by this Court. The decision below was correct and resulted from proper application of well-established patent law principles. Petitioner's complaint is simply with the result of an inquiry that is inevitably context-specific. Petitioner complains that the Federal Circuit's decision construing claims as they were drafted results in the claims covering a device not mentioned in the patent specifications, not invented by the patent applicants, and unknown in the art at time the original application was filed. Petitioner is again wrong. First, it is uncontested that L-F was the first to invent a front-loading powered medical injector and that the claims asserted in this action are directed to that broad invention. Second, the record below fully supported the fact that the inventors had conceived of both design alternatives, i.e., with and without a pressure jacket. The patent statute, however, requires only that a patentee describe a single mode for carrying out the invention. 35 U.S.C. § 112. Third, whether or not the patentees conceived of a version without a pressure jacket is wholly irrelevant for it is axiomatic that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121-22 (Fed. Cir. 1985). As this Court stated in *Smith v. Snow*:

> We may take it that, as the statute requires, the specifications just detailed show a way of using the inventor's method and that he conceived that particular way described was the best one. But he is not confined to that mode of use since the claims of the patent, not its specifications, measure the invention.

294 U.S. at 11 (citations omitted).

II. The Decision In This Case Is Not In Conflict With The Federal Circuit's Decision in *Microsoft Corp. v. Multi-Systems, Inc.*

Claim construction, of necessity, is an intensely context-specific exercise. Different patents for different inventions have different claims, different specifications and different prosecution histories. Statements made and actions taken in one case are wholly likely to be missing in another.

In *Microsoft Corp. v. Multi-Systems, Inc.*, 357 F.3d 1340 (Fed. Cir. 2004), the Federal Circuit reviewed the claims and specifications of the three patents in suit and the patentee's statements during prosecution and reached the "inescapable conclusion" that the descriptions did not merely describe a preferred embodiment, "but more broadly described the overall inventions of all three patents." *Id.* at 1348. This determination was based in part on claim language of the '627 patent that "explicitly states that the transmission of data . . . between the local site and a remote site must occur 'over a telephone line.' " *Id.* at 1348, and the patentee's concession that all of the claims require the use of a standard telephone line (whether expressly recited in the claims or not), and statements made in the prosecution history of the '627 patent. *Id.* at 1349.

The Federal Circuit in *Microsoft* applied the same approach to claim construction as it did in this case. It thoroughly examined the claims, specifications and prosecution histories and determined that transmission of data "over a telephone line" was not just a preferred embodiment. *Microsoft* is thus not unlike other Federal Circuit cases cited and distinguished by the Federal Circuit in its decision

in this case. (Pet. App. 14-18). There is no conflict, simply different records.[6]

III. Petitioner's Argument That The Federal Circuit's Decision Erodes The Role Of The PTO And The Patent System Is Misplaced

Petitioner argues that part of the PTO's function is to reject any claims it finds are unsupported by the specification and, should a court construe claims broadly (i.e., as they were written and allowed by the PTO), that this function is somehow compromised. This argument lacks credibility in the abstract and in particular has no application in this case.

As the Federal Circuit pointed out in its analysis with respect to the '669 and '261 patents, the PTO Examiner had before him independent claims that did not recite a pressure jacket and dependent claims that included the recitation of a pressure jacket. Accordingly, the PTO Examiner clearly knew the scope of the claims he was issuing. In addition, as the Federal Circuit also pointed out, in the prosecution of the '261 patent, the applicants stated to the PTO Examiner that in the claimed devices there is not "necessarily a pressure jacket." (Pet. App. 20-21). The PTO Examiner never rejected any of these claims as being unsupported by the specification. The simple reason is that the claims clearly are supported under the patent statute.

Petitioner further argues that the decision below erodes the patent system itself by eroding its notice function. Again, this argument carries no weight. All of the claims of the four

6. It is difficult to understand how these two cases can represent an "intracircuit split" when two of the three judges were common to both panels and the decisions were issued within days of each other.

patents in suit were thoroughly examined by the PTO and issued without limitation to a pressure jacket or direct use of electrical signals in the injector control circuitry. Thus, the public was and is clearly on notice as to the scope of the claims. As issued by the PTO, they are not limited in the manner that Petitioner seeks to limit them.

Petitioner forgets that it is Petitioner who seeks to alter the plain scope of the claims issued by the PTO. Thus, there is no lack of notice to the public — only Petitioner's refusal to recognize the well-settled rules applicable in the PTO and in the courts that, under the patent statute, only a single embodiment need be described and that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Rexnord*, *supra.*

IV. Petitioner's Request That The Petition Be Either Granted Or Held Or Granted And The Judgment Vacated And Remanded Should Be Denied.

Lastly, Petitioner argues that the Federal Circuit's grant of an *en banc* rehearing in *Phillips v. AWH Corp.*, Federal Circuit Appeal Nos. 03-1269,-1286, should be grounds for either granting its petition, holding it or granting it, vacating the judgment and remanding pending the Federal Circuit's *en banc* opinion. *Phillips* is not grounds for granting any of Petitioner's requests.

First, this case did not involve competing technical or general purpose dictionaries or any other definitional sources. There was no dispute over the meaning of the words "opening", "related to," or "using." Petitioner's own '858 patent used the word "opening" as simply the portion of an injector housing for

receiving the rearward end of the syringe, with or without a pressure jacket.[7] All parties agreed that the asserted independent claims did not recite a pressure jacket limitation while certain dependent claims did. By applying the doctrine of claim differentiation, the Federal Circuit found strong support for the patentees' position that its independent claims were not limited as argued by Petitioner because it would have been redundant for the independent claims to have been limited to a scope of protection already provided by the dependent claims. Nothing similar is present in the *Phillips* appeal.

Nor did *Phillips* involve competing claim construction methodologies. Regardless of how the Federal Circuit answers the questions it poses regarding the appropriate use of dictionaries in claim construction, this Court's precedent cited above remains. Further, should *Phillips* be reversed and Judge Dyk's dissenting opinion be adopted, that result will not help Petitioner since Judge Dyk refused to read into the claims the limitations of the preferred embodiment as Petitioner seeks to do here.

Second, Petitioner had filed its own petition for rehearing *en banc*, which was pending shortly before the opinion in *Phillips* was issued. If there were some application of the questions posed by the *en banc* panel in *Phillips* to this case, Petitioner's petition for rehearing *en banc* would have been granted.

Third, the Federal Circuit itself is not withholding decisions on claim construction pending an *en banc* ruling in *Phillips*. Claim construction opinions are being issued by

---

7. "[T]he injector housing 26 is provided with an essentially cylindrical opening 29 for receiving a rearward end of the syringe 22." (Opp. App. 8, col. 4, l. 19-21).

the Federal Circuit weekly with no mention that decisions regarding claim construction should be held up because of *Phillips*.[8] If the Federal Circuit is not holding claim construction decisions pending *Phillips*, there is no good reason for this Court to hold petitions for writ of certiorari from those decisions. Granting or holding petitions in this Court can only create a massive backlog of petitions. Granting petitions, vacating the judgments and remanding will only shift that backlog to the Federal Circuit.

Finally, the Federal Circuit's decision in this case only reversed a grant of summary judgment and remanded the case back to the district court. No trial date has been set, but it will be well into 2005. Petitioner will have ample opportunity to assess whatever applicability the Federal Circuit's *en banc* opinion in *Phillips* may have.

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8. *See, e.g., Glaxo Group Ltd. v. Apotex, Inc.*, 2004 U.S. App. Lexis 15489 (Fed. Cir. July 27, 2004); *Mars, Inc. v. H.J. Heinz Co.*, 2004 U.S. App. Lexis 15640 (Fed. Cir. July 29, 2004); *Elster Electricity LLC v. Schlumbergersema Inc.*, 2004 U.S. App. Lexis 15796 (Fed. Cir. July 30, 2004); *Neomagic Corp. v. Trident Microsystems, Inc.*, U.S. App. Lexis 16178 (Fed. Cir. August 5, 2004); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 2004 U.S. App. Lexis 16549 (Fed. Cir. August 11, 2004); *Power Mosfet Technologies, LLC v. Siemens AG*, 2004 U.S. Lexis 17020 (Fed. Cir. August 17, 2004).

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be denied.

Respectfully submitted,

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SEP 13 2004

No. 04-32

In The

Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY and MALLINCKRODT, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF

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REPLY

Pursuant to Supreme Court Rule 15.6, Petitioner Medrad hereby submits this Reply Brief in support of Medrad's Petition for Writ of Certiorari filed on July 1, 2004, to address new points raised in the Brief in Opposition.

Respondents' Brief in Opposition includes a number of factual and legal errors that are material to the current petition.[1] Most important of these is Respondents' contention that the law on claim construction is "well-settled" and that this case simply involved application of these "well-settled" principles to its specific facts. That contention, which permeates Respondents' entire brief, is not credible. As set forth in Medrad's Petition and Supplemental Brief, and as evidenced in the Federal Court's decision to hear seven disputed claim construction questions *en banc* in *Phillips v. AWH Corp.*, Federal Circuit Appeal Nos. 03-1269, -1286 (App. 139-60), the law on claim construction is not "well-settled" at all.

Those unsettled and conflicting claim construction principles are, moreover, at the heart of the resolution of this case. This case, which is extensively cited in the

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[1] Respondents apparently recognized the weakness and vulnerability of their Opposition, relying as they do on errors and misrepresentations. In violation of Sup. Ct. R. 29.3, Respondents filed their Brief in Opposition with this Court via overnight delivery service on September 2, but served Medrad via regular U.S. mail. This tactic ensured that Medrad would not receive Respondents' Brief until after the long Labor Day weekend on September 7, five days after the Brief in Opposition was docketed and 4 days after it was received by this Court, thereby depriving Medrad of a significant portion of the 10 day window for filing a reply brief set forth in Sup. Ct. R. 15.5. Notwithstanding, Medrad is filing this Reply Brief within the 10 day window.

Phillips' dissent and cited in other Federal Circuit opinions as well, plainly contains holdings that have far-reaching consequences well beyond its specific facts. There is no other way to explain the Federal Circuit's repeated reliance on the analysis in this case. Given the timing of the *Phillips en banc* decision and the direct relationship between the claim construction issues raised in the cases, this Court should either hold its review of Medrad's Petition until after the *Phillips en banc* decision is rendered or grant Medrad's Petition, vacate the Federal Circuit's opinion, and remand this case back to the Federal Circuit to reconsider in light of the holdings in the *Phillips en banc* decision.

I. THE LAW ON PATENT CLAIM CONSTRUCTION IS FAR FROM WELL-SETTLED AND REFLECTS IRRECONCILABLE CONFLICTS

Respondents' argument that the law of claim construction is "well-settled" ignores almost everything that has occurred in that area of the law since this Court's decision *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Specifically, the Federal Circuit's decision to hear the *Phillips* case *en banc* to "resolve issues concerning the construction of patent claims" and the Federal Circuit's identification of seven questions (App. 133-38) – all involving the issue of claim construction – is only the most recent indication that claim construction is not "well-settled." The dissent's assertion in *Phillips* that the "majority decision" in *Phillips* "effectively limits the claims to the preferred embodiment, contrary to our recent decision in *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004), and numerous other decisions of this court," *Phillips v. AWH Corp.*, 363 F.3d 1207, 1216 (Fed. Cir.

2004) (App. 155), simply underscores that the law on claim construction is far from settled and places this case squarely in the middle of that unsettled area.

The Federal Circuit has also acknowledged that the claim construction at issue in this case involves a "fine line" and an "inherent tension" between two axioms of claim construction: that claim terms should be read in view of the specification but that it is improper to read a limitation from the specification into the claims. *See Liebel-Flarsheim*, 358 F.3d at 904-05. The Federal Circuit noted that this tension creates a problem that can present "particular difficulties" in a case such as this one where the preferred embodiment is the only embodiment, but the claim language is sufficiently broad that it might be read to encompass features not disclosed in the written description. *Id.* at 905. Even more recently, the Federal Circuit acknowledged that the "contrasting nature of the axioms" has been a "longstanding difficulty." *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 2004 WL 1780928, *5 (Fed. Cir. Aug. 11, 2004).

Given the Federal Circuit's decision to rehear *Phillips en banc* on seven claim construction issues, the Federal Circuit's own acknowledgment of a "longstanding difficulty" in claim construction, and the various commentators' explanations that the Federal Circuit's decisions are in conflict that Medrad cited in its Petition, Respondents' position that claim construction, and in particular the claim construction at issue here, is "well-settled" is simply untenable.

II. THE HOLDINGS IN THIS CASE REACH BEYOND ITS FACTS AND ARE DIRECTLY AT ISSUE IN THE *PHILLIPS EN BANC* DECISION

Respondents' characterization of the arguments that Medrad is presenting as "case-specific issues not appropriate for review by this Court" ignores the recognition that this case already has received and this case's relationship to the issues in *Phillips*.

Since its publication in February of 2004, the Federal Circuit's decision in this case has been cited no less than ten times by the Federal Circuit and eight times by Federal District Courts.[2] Commentators have also cited this case a significant number of times. For example, one commentator included it as part of his recent article in his

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[2] *Phillips v. AWH Corp.*, 363 F.3d 1207 (Fed. Cir. 2004); *Home Diagnostics, Inc. v. Lifescan, Inc.*, 2004 WL 1925613 (Fed. Cir. Aug 31, 2004); *In re Bigio*, 2004 WL 1878752 (Fed. Cir. Aug 24, 2004); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 2004 WL 1780928 (Fed. Cir. Aug 11, 2004); *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369 (Fed. Cir. 2004); *Zimmer, Inc. v. Howmedica Osteonics Corp.*, 2004 WL 1194248 (Fed. Cir. May 26, 2004); *In re American Academy of Science Tech Center*, 367 F.3d 1359 (Fed. Cir. 2004); *Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348 (Fed. Cir. 2004); *Novartis Pharmaceuticals Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306 (Fed. Cir. 2004); *Gaus v. Conair Corp.*, 363 F.3d 1284 (Fed. Cir. 2004); *Rambus, Inc. v. Infineon Technologies AG*, 2004 WL 1822386 (E.D. Va. Aug 12, 2004); *Honeywell Intern, Inc. v. ITT Industries, Inc.*, 2004 WL 1774773 (E.D. Mich. Aug 5, 2004); *Lifetime Products, Inc. v. GSC Technology Corp.*, 321 F.Supp.2d 938 (N.D. Ill. 2004); *Dow Agrosciences LLC v. Crompton Corp.*, 2004 WL 1087362 (S.D. Ind. May 12, 2004); *AGFA Corp. v. Creo Products, Inc.*, 2004 WL 1882623 (D. Mass. Aug 24, 2004); *Agere Systems, Inc. v. Broadcom Corp.*, 2004 WL 1658530 (E.D. Pa. Jul 20, 2004); *Lifetime Products, Inc. v. Correll, Inc.*, 323 F.Supp.2d 1129 (D. Utah Jun 30, 2004); and *Ardisam, Inc. v. Ameristep, Inc.*, 2004 WL 1725166 (W.D. Wis. Aug 2, 2004).

"Federal Circuit Claim Construction Canon Outline." Jonathan R. Spivey, *The Federal Circuit's Markman Jurisprudence – Patchwork Quilt or Jigsaw Puzzle? Is There Really Panel-Dependency and Unpredictability in Federal Circuit Opinions?* 795 PLI/Pat 709, 723. Yet another commentator indicated that the Federal Circuit's decision in this case sent a "strong message" on an issue of claim construction. *Cases and Recent Developments*, 13 Fed. Cir. B. J. 719, 762.

The citation of this case a significant number of times in such a short time period confirms that this is an important case in the area of claim construction and not simply a run of the mill application of "well-settled" law to specific facts.

Moreover, given that the dissent in *Phillips* cited this case eight times, *see Phillips* 363 F.3d at 1216-19 (App. 154-60), and the identity of the issues involved in these two cases as set forth in Medrad's Supplemental Brief, there is little question that the Federal Circuit's decision in this case will play a role in the Federal Circuit's *en banc* decision in *Phillips*. Maintaining close contact between this case and *Phillips* will ensure that this case remains consistent with the jurisprudence of claim construction that will result from the *en banc* decision in *Phillips*.

In sum, given the significant number of citations to this case in such a short period and the commonality of issues between this case and the issues to be considered *en banc* by the Federal Circuit in *Phillips*, Respondents' argument that the Petition for Certiorari should simply be denied is without merit.

III. RESPONDENTS MISSTATE A NUMBER OF MATERIAL FACTS IN A FAILED ATTEMPT TO DISTINGUISH THIS CASE FROM *PHILLIPS*

It is clear on the record that the Federal Circuit relied on an extrinsic dictionary definition to expand the coverage of Respondents' patent claims to cover an invention that Respondents' inventors did not invent. That outcome places this case squarely within the issues to be addressed by the Federal Circuit *en banc* in *Phillips* and squarely in conflict with this Court's precedent in *Markman*. Respondents misstate a number of material facts to try to avoid this conclusion.

First and foremost, Respondents incorrectly suggest that this case was not "decided based on extrinsic dictionary definitions." *See* Opposition Brief at 12. The record is clear, however, that the Federal Circuit's construction of the term "opening" as simply an "aperture" in "common usage," *Liebel-Flarsheim*, 358 F.3d at 905, was based upon the extrinsic dictionary definition of "opening" cited by the District Court. (App. 51) (*citing* Webster's Third New International Dictionary).

Second, Respondents wrongly argue that Medrad was "unable" to "point to a clear disavowal of claim scope in either the written description or the prosecution histories." *See* Opposition Brief at 12. Medrad specifically submitted written citations to the record clearly pointing out where the disavowal of claim scope could be located in the written descriptions and prosecution histories of the patents in issue. (App. 165-66).

Third, Respondents incorrectly argue that it is "uncontested" that "L-F was the first to invent a front-loading

powered medical injector and that the claims asserted in this action are directed to that broad invention." *See* Opposition Brief at 18. Medrad has always argued that L-F's invention, and the claims of its patents, are limited to a front-loading powered medical injector *with a pressure jacket*. (App. 49). In fact, the district court specifically noted that it was Medrad who, at a trade show in November 1992, "introduced the first pressure jacketless, front-loading CT injector system for disposable syringes." (App. 39).

Fourth, Respondents incorrectly assert that "the record below fully supported the fact that the inventors had conceived of both design alternatives, i.e., with and without a pressure jacket." *See* Opposition Brief at 18. The record below is clear that the inventors for the Respondents never got an injector without a pressure jacket to work and abandoned the idea. As one of Respondents' inventors admitted in an internal memorandum well after Respondents filed their patent: "We investigated in the beginning the possibility of not using a pressure sleeve [i.e., jacket]. Our testing indicated that this option was too risky. . . ." (App. 167).

Given a correct rendition of the facts, this case clearly involves the same issues the Federal Circuit will address *en banc* in *Phillips*; namely, whether it is appropriate to look first and foremost to intrinsic evidence or extrinsic dictionary definitions in defining claim terms. Given this alignment with the issues in *Phillips* and the conflict between the Federal Circuit's decision in this case and this Court's precedent in *Markman*, the issues raised in Medrad's petition are appropriate for consideration and review by this Court or at least for preservation pending the *en banc* decision in *Phillips*.

IV. CONCLUSION

The current state of the law on claim construction is not "well-settled" as Respondents suggest. As evidenced by the Federal Circuit's decision to address seven fundamental questions on claim construction *en banc* in *Phillips v. AWH Corp.*, the law on claim construction is in conflict. Given the far-reaching holding in this case and the direct connection between the issues in this case and *Phillips*, this Court should either hold Medrad's Petition for review until after the *Phillips en banc* decision is rendered or grant Medrad's Petition, vacate the Federal Circuit's opinion and remand this case to the Federal Circuit as Medrad requested.

DATED: September 10, 2004

Respectfully submitted,

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(Filed Nov. 7, 2003)

November 6, 2003

Via Hand Delivery

Mr. Jan Horbaly
Clerk of Court
United States Court of Appeal
for the Federal Circuit
717 Madison Place, N.W.
Washington, DC 20439

RE: Liebel-Flarsheim Company et al. v. Medrad, Inc., Appeal Nos. 03-1082, -1165

Dear Mr. Horbaly:

During oral argument in the above-captioned appeal on Tuesday morning, November 4, 2003, Judge Dyk asked where in the '669 and '261 patents appellee Medrad finds support for the District Court's construction of the claims terms "syringe receiving opening" and "opening." At that time, I did not have the particular pin-point citations to the intrinsic evidence of record available to me at the podium. The following are those pin-point citations:

In the '669 patent:

Column 2, line 64 to Column 3, line 1 (A0183-A0184).
Abstract, lines 1-10 (A0171).

In the '261 patent:

> Column 2, lines 61-65 (A0205).
> Abstract, lines 1-10 (A0193).

In the prosecution history of L-F's Original Patent Application, to which the '669 and '261 patents claim priority:

> Page 39 and the original 89 claims (A3025-A3072) viewed in conjunction with:
>
> amended claims 109 (A3109-A3110) and 114 (A3111-A3112) that were added in the prosecution of the original application by an Amendment (A3103-A3116); and
>
> the "Remarks" and claims in a Supplemental Amendment (A3121-A3137) filed during prosecution of the original application and in particular, the statement that "The claims proposed at the interview, which are claims 119-125, are more concise than those they replace and clarify the inventive concepts claimed." (A3131)

In the prosecution history of the '261 Patent:

> The statement in the "remarks" portion of a Preliminary Amendment (A2510-A2526) that: "This divisional application is filed to more particularly claim embodiments of the invention not previously specifically claimed, particularly as illustrated in Figs. 15-17 of the drawings of the application, and particularly described on page 37, line 21 to page 39, line 3 of the specification of the application." (A2525)

We hereby respectfully request that these pin-point citations be provided to Judges Lourie, Dyk and Bryson who sat on the panel that heard the oral argument in the

above-captioned appeal. Thank you in advance for your attention to this matter.

HOWREY SIMON ARNOLD &
WHITE LLP

By: /s/ James F. Davis
James F. Davis

cc J. Robert Chambers, Esq.
(via facsimile)

Liebel-Flarsheim **LF**
Interoffice Memo

TO Dane Battiato DATE December 4, 1992
FROM Frank Fago SUBJECT Medrad Front Load Injector

As we have seen, Medrad has shown a front load injection system at the RSNA. Attached is a sketch that illustrates their configuration. The attributes of Medrad front load system include;

- 200 ml
- Adapts to there existing injector
- Requires no pressure sleeve
- Mounted at the rear flange
- Built in catheter retention system
- Clear
- Gamma Sterilizable
- Split cavity mold

Syringe Material

An engineer from Medrad told me that their syringe material was PET (Polyethyiene terephthalate). PET is a good candidate for a syringe since it is clear, has good chemical resistance, is gamma resistant, and has good mechanical properties. The original material we selected for the syringe barrel was Ektar, which is in the PET family. We ended up not using Ektar for the syringe because our molder couldn't reliably run the material. Unfortunately, there is no turning back since the shrink rates are dramatically different. (*Polypropylene = .020 in/in; PET = .004 in/in*)

Cost

I believe that Medrad's syringe costs is about the same as ours. Their increased cost incurred due to additional and more expensive material along with an increased mold cycle time is offset by our additional costs for the Umbrella Cap and Nut. (*PET costs about 12.8 ¢/in^3 verses 1.4 ¢/in^3 for Polypropylene.*)

Structural Integrity

We investigated in the beginning the possibility of not using a pressure sleeve. Our testing indicated that this option was too risky at 300 psi due to syringe ballooning and the possibility of blow by. Medrad's maximum pressure is probably no greater than 200 psi. Even at pressures of 200 psi there is still a problem with ballooning which increases the time that contrast continues to flow after the injection is stopped.

User Interface

Our CT9000 user interface and console is far superior to Medrad's including a shorter cycle time. Our plunger is located at the top of the syringe which reduces the cycle time. They have wasted time to expel air before filling the syringe and the time to retract the ram after the injection so another syringe can be loaded. They will not be able to move the plunger to the top of the syringe with there present system because

* * *

(3)

Supreme Court, U.S.
FILED
AUG - 5 2004
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No. 04-32

In The
Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

SUPPLEMENTAL BRIEF RELATING TO NEW DEVELOPMENTS IN THE FEDERAL CIRCUIT IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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SUPPLEMENTAL BRIEF

Pursuant to Supreme Court Rule 15.8, Petitioner Medrad hereby submits this Supplemental Brief relating to a new and critical development on the patent claim construction issues raised in Medrad's Petition for Writ of Certiorari filed on July 1, 2004.

Specifically, on July 21, 2004, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") entered an Order (App. 133-38) granting the Plaintiff-Appellant's petition to rehear the appeal *en banc* in *Phillips v. AWH Corp.*, Federal Circuit Appeal Nos. 03-1269, -1286, and vacating the April 8, 2004 judgment of the court reported at *Phillips v. AWH Corp.*, 363 F.3d 1207 (Fed. Cir. 2004). (App. 139-60). In this Order, the Federal Circuit stated that it determined to hear the *Phillips* case *en banc* "in order to resolve issues concerning the construction of patent claims raised by the now-vacated panel majority and dissenting opinions." (App. 134). The Federal Circuit then listed seven questions related to the claim construction issues that it intended to address – each one relating to the import of its current claim construction jurisprudence. (App. 134-136).

What is most remarkable about the seven questions that will be involved in the *en banc* proceeding is the extent to which they overlap the patent claim construction issues first raised by Medrad in its petition. What is equally apparent, however, is that the grant of *en banc* review in *Phillips* has removed any doubt on the significance and import of the claim construction issues raised by Medrad in its petition.

There likewise is no doubt that the decision on review in this Court resides at the center of the controversy of the

claim construction issues identified by the Federal Circuit. Medrad cited and referred to *Phillips* in its petition as illustrative of the conflicts in the Federal Circuit's claim construction jurisprudence. *See* Medrad's Petition for Writ of Certiorari, at 22. Judge Dyk's dissent in *Phillips* also referred to the reasoning in this case as illustrative of why the majority's opinion was wrong. *See Phillips*, 363 F.3d at 1216-19 (App. 154-60).

Presumably the Federal Circuit in *Phillips* intends to settle the myriad problems its claim construction decisions have generated. Any precedent established in *Phillips* plainly would have controlled the Federal Circuit's decision here. Given the similarity of the issues raised and the timing of Medrad's petition, it would be a grave injustice to Medrad if any decision in its case were entered without the benefit of consideration of the Federal Circuit's *en banc* decision in *Phillips*.

For these reasons, Petitioner Medrad respectfully requests that this Court either hold its review of this petition until after the Federal Circuit issues its *en banc* decision in *Phillips*, or, grant Medrad's Petition for Writ of Certiorari, vacate the Federal Circuit's decision in this case (App. 1-34), and remand this case to the Federal Circuit to reconsider its judgment in light of the *en banc* ruling in *Phillips*. The Federal Circuit's decision to consider the *Phillips* case *en banc* is certainly one of those unique circumstances in which remand to the Federal Circuit is appropriate. *See, e.g., Alabama v. Ritter*, 454 U.S. 885 (1981) (remand in light of intervening state court decision).

I.

THE QUESTIONS PRESENTED IN THIS CASE RELATE DIRECTLY TO THE ISSUES TO BE ADDRESSED IN *PHILLIPS*

Medrad's petition highlights the longstanding and recurring conflicts that have plagued the Federal Circuit's claim construction jurisprudence since the decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Pivotal among those conflicts is the emergence of the Federal Circuit's "ordinary meaning" line of cases which places paramount and exclusive reliance on abstract dictionary definitions in resolving claim construction disputes. That line of authority proved pivotal in the decision from which Medrad seeks this Court's review. Medrad's petition also underscored that the time to resolve these conflicts is now because of the deleterious impacts they engender for courts, litigants, businesses, and the patent system.

With its grant of *en banc* review in *Phillips*, the Federal Circuit seemingly agrees. It has asked the parties and any amici to brief seven questions, each one of which is implicated by the questions raised by Medrad's petition. For example, Medrad's first question presented in its Petition asked:

> Whether the outcome determinative "intracircuit split" within the Federal Circuit on patent claim construction should be resolved to eliminate the current unpredictable and inefficient legal environment and promote the "intrajurisdictional certainty" contemplated by *Markman*?

Medrad's Petition for Writ of Certiorari, at ii.

Compare that with the fourth question set forth in the *en banc* Order in *Phillips*:

> Instead of viewing the claim construction methodologies in the majority and dissent of the now-vacated panel decision as alternative, conflicting approaches, should the two approaches be treated as complementary methodologies such that there is a dual restriction on claim scope, and a patentee must satisfy both limiting methodologies in order to establish the claim coverage it seeks?

(App. 135).

The "intra-jurisdictional split" referenced by Medrad in its Petition is the same as the "two approaches" to "claim construction methodologies" referenced by the Federal Circuit in *Phillips* – namely, an approach that determines the meaning of disputed claim terms based on their "ordinary" or "plain meaning," versus an approach that determines the meaning of those terms based on what the inventor actually invented and disclosed in the patent. Judge Dyk's dissent in *Phillips* proves the point when he cites *Liebel-Flarsheim* no less than eight times in arguing that:

> The majority decision effectively limits the claims to the preferred embodiment, contrary to our recent decision in *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004), and numerous other decisions of this Court.

Phillips, 363 F.3d at 1216 (App. 154-55); *see also id.* at 1216-19 (App. 154-60).

Then, look at Medrad's second question presented in its Petition:

> Whether disputed terms in a patent claim should be construed by looking first and principally to the "intrinsic evidence" (*i.e.*, the patent's claim language, specification, and prosecution history), or by looking first and principally to extrinsic dictionary definitions to determine the term's "ordinary meaning," and then consulting the intrinsic evidence merely to determine if it contains a "manifest exclusion or restriction" of that "ordinary meaning"?

Medrad's Petition for Writ of Certiorari, at ii-iii (citations omitted).

Compare that to the Federal Circuit's first question set forth in the *en banc* Order in *Phillips*:

> Is the public notice function of patent claims better served by referencing primarily to technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee's use of the term in the specification? If both sources are to be consulted, in what order?

(App. 134).

The second and third questions set forth in the *en banc* Order in *Phillips* (App. 134-35), both basically a subset of the first question, likewise address the same issues – namely the particular methodologies of using dictionaries and the patent's specification – that are raised by Medrad's second question presented.

Finally, Medrad's third question asked:

> Whether a patent claim should be broadly construed based on a dictionary-defined "ordinary meaning" to cover a device that was (a) not mentioned anywhere in the patent's specification, (b) not invented by the patent applicants, and (c) unknown in the art at the time that the patent was filed?

Medrad's Petition for Writ of Certiorari, at iii. Compare that to the fifth and sixth questions raised by the Federal Circuit in the *en banc* Order in *Phillips*:

> 5. When, if ever, should claim language be narrowly construed for the sole purpose of avoiding invalidity under, e.g., 35 U.S.C. §§ 102, 103 and 112?
>
> 6. What role should prosecution history and expert testimony by one of ordinary skill in the art play in determining the meaning of the disputed claim terms?

(App. 135). Although Medrad's third question is not encompassed in total by these two issues, the core of Medrad's third question is implicated directly.

Specifically, the failure to mention a device in the patent's specification that the claims are construed to cover (as happened in Medrad's case) likely means that the claims are invalid for lack of written description and/or enablement under 35 U.S.C. § 112, the issue raised in question 5 of the *en banc* Order in *Phillips*. The panel in Medrad specifically addressed this exact question when it wrote that "unless the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous, the axiom regarding the construction to

preserve the validity of the claim does not apply." *Liebel-Flarsheim*, 358 F.3d at 911 (App. 24).

Similarly, the issue of lack of invention by the patentee and its effect on claim construction as raised in Medrad's third question implicates question 5 in *Phillips* since lack of invention invokes 35 U.S.C. § 102. Likewise, the issue of whether a device was known in the art at the time of the alleged invention and its effect on claim construction, as raised by Medrad's third question, implicates question 6 in *Phillips*, since expert testimony and the testimony of persons skilled in the art are used to establish the state of the art.

Finally, as Medrad emphasized throughout its petition, the Federal Circuit accorded no deference to any aspect of the district court's claim construction methodology and departed materially from the claim construction methodology endorsed by this Court's reasoning in *Markman*.

Compare that emphasis with question 7 in *Phillips*:

> Consistent with the Supreme Court's decision in Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), and our *en banc* decision in Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448 (Fed. Cir. 1998), is it appropriate for this court to accord any deference to any aspect of trial court claim construction rulings? If so, on what aspects, in what circumstances, and to what extent?

(App. 136).

In light of this direct comparison, there is little if any doubt that the issues raised in Medrad's petition overlap –

and overlap remarkably – with the issues raised in the Federal Circuit's *en banc* order issued just 20 days after Medrad's petition was filed. Medrad went to great pains to illustrate that its petition presented a real, concrete and significant controversy. The *en banc* order in *Phillips* confirms that that is the case.

II.

CONSIDERATIONS OF TIMING AND JURISPRUDENTIAL UNIFORMITY WARRANT A HOLD OF THIS COURT'S DECISION ON MEDRAD'S PETITION OR A GRANT, VACATE AND REMAND

Given the similarity of the issues involved and the timing of the Federal Circuit's *en banc* consideration in the *Phillips* case, this Court should either hold review of Medrad's Petition until after the Federal Circuit issues an *en banc* decision in *Phillips* or grant Medrad's Petition for Writ of Certiorari, vacate the Federal Circuit's decision in Medrad and remand the case to the Federal Circuit for reconsideration in light of the *en banc* decision in *Phillips*.

There is no dispute that the resolution of the seven questions in *Phillips* will have a direct bearing on the issues raised in Medrad's petition and, indeed, the resolution of Medrad's claim construction dispute. *Phillips* will provide the definitive expression on what principles the Federal circuit believes should control in claim construction disputes.

Recognizing the fact that Medrad was the first to raise the same issues in its petition for rehearing *en banc* (App. 161-164) and its petition for writ of certiorari, it would be

a grave injustice to Medrad if the issues it raised are not considered in light of whatever decision the Federal Circuit, sitting *en banc*, reaches in *Phillips*.

Medrad therefore respectfully requests that this Court either: (1) hold its review of the Petition until after the Federal Circuit issues its *en banc* decision in *Phillips* and permit the parties to file supplemental briefs on the import of that *en banc* decision on the issues raised in the petition; or (2) grant Medrad's Petition, vacate the Federal Circuit's decision at issue in this case, and remand this case to the Federal Circuit to reconsider its judgment in this case in light of the anticipated *en banc* decision in *Phillips*.

III.

CONCLUSION

In dealing with pending certiorari petitions, this Court has the discretion to take intervening developments into account. The grant of *en banc* review in *Phillips* is one illustration of just such a development. Given the timing of the Federal Circuit's order and the pendancy of Medrad's petition, the interests of justice, jurisprudential uniformity, and judicial economy will be served by granting the relief Medrad requests.

DATED: August 5, 2004

Respectfully submitted,

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United States Court of Appeals
for the Federal Circuit

03-1269, -1286

EDWARD H. PHILLIPS,

Plaintiff-Appellant,

v.

AWH CORPORATION, HOPEMAN BROTHERS, INC., and LOFTON CORPORATION

Defendants-Cross Appellants.

Carl F. Manthei, Attorney at Law, of Boulder, Colorado, filed a petition for rehearing en banc for plaintiff-appellant.

Mark W. Fischer, Faegre & Benson LLP, of Boulder, Colorado, filed a response to the petition for defendants-cross appellants. With him on the response was Scott Holwick.

Appealed from: United States District Court for the District of Colorado

Judge Marcia S. Krieger

Before MAYER, Chief Judge, NEWMAN, MICHEL, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

ORDER

A combined petition for panel rehearing and rehearing en banc having been filed by the Plaintiff-Appellant, and a response thereto having been invited by the court and filed by the Defendants-Cross Appellants, and the petition for rehearing having been referred to the panel that heard the

appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service, and a poll having been taken

IT IS ORDERED THAT:

(1) the petition for rehearing is denied;

(2) the petition to rehear the appeal en banc is granted;

(3) the judgment of the court entered on April 8, 2004, is vacated, and the opinion of the court accompanying the judgment, reported at 363 F.3d 1207 (Fed. Cir. 2004), is withdrawn.

This court has determined to hear this case en banc in order to resolve issues concerning the construction of patent claims raised by the now-vacated panel majority and dissenting opinions. The parties are invited to submit additional briefs directed to these issues, with respect particularly to the following questions:

1. Is the public notice function of patent claims better served by referencing primarily to technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee's use of the term in the specification? If both sources are to be consulted, in what order?

2. If dictionaries should serve as the primary source for claim interpretation, should the specification limit the full scope of claim language (as defined by the dictionaries) only when the patentee has acted as his own lexicographer or when the specification reflects a clear disclaimer of claim scope? If so, what

language in the specification will satisfy those conditions? What use should be made of general as opposed to technical dictionaries? How does the concept of ordinary meaning apply if there are multiple dictionary definitions of the same term? If the dictionary provides multiple potentially applicable definitions for a term, is it appropriate to look to the specification to determine what definition or definitions should apply?

3. If the primary source for claim construction should be the specification, what use should be made of dictionaries? Should the range of the ordinary meaning of claim language be limited to the scope of the invention disclosed in the specification, for example, when only a single embodiment is disclosed and no other indications of breadth are disclosed?

4. Instead of viewing the claim construction methodologies in the majority and dissent of the now-vacated panel decision as alternative, conflicting approaches, should the two approaches be treated as complementary methodologies such that there is a dual restriction on claim scope, and a patentee must satisfy both limiting methodologies in order to establish the claim coverage it seeks?

5. When, if ever, should claim language be narrowly construed for the sole purpose of avoiding invalidity under, e.g., 35 U.S.C. §§ 102, 103 and 112?

6. What role should prosecution history and expert testimony by one of ordinary skill in the art play in determining the meaning of the disputed claim terms?

7. Consistent with the Supreme Court's decision in Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), and our en banc decision in Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448 (Fed. Cir. 1998), is it appropriate for this court to accord any deference to any aspect of trial court claim construction rulings? If so, on what aspects, in what circumstances, and to what extent?

This case will be heard en banc on the basis of the briefs already filed and any additional briefs addressing the questions set forth above. An original and thirty copies of all additional briefs shall be filed, and two copies served on opposing counsel. Such additional briefs shall be filed simultaneously by the parties, sixty days from the date of this Order, and shall not exceed 7,000 words in length.

Amicus curiae briefs may be filed by bar associations, trade or industry associations, government entities, and other interested parties. In particular, the United States Patent and Trademark Office is invited to submit an amicus curiae brief. Amicus briefs shall be limited to 5,000 words, and shall be filed within sixty days from the date of this Order. Amicus briefs shall comply with Fed. R.App. P. 29 and Federal Circuit Rule 29. In order to reduce the number of redundant briefs, the court requests that, whenever possible, amicus participants advocating similar positions file a joint brief.

Both the parties' briefs and the amicus briefs shall be limited to the issue of claim construction, and shall not address the issue of whether the plaintiff-appellant's trade secret misappropriation claim was barred by the statute of limitations.

Oral argument will be scheduled by a later order.

RADER, Circuit Judge, concurs in a separate opinion.

MAYER, Chief Judge, dissents in a separate opinion.

FOR THE COURT,

July 21, 2004
Date

Jan Horbaly
Jan Horbaly
Clerk

RADER, Circuit Judge, concurring in this court's order to rehear the appeal en banc.

To provide completeness in the en banc proceeding, this court should receive commentary on the following question as well:

> Is claim construction amenable to resolution by resort to strictly algorithmic rules, e.g., specification first, dictionaries first, etc.? Or is claim construction better achieved by using the order or tools relevant in each case to discern the meaning of terms according to the understanding of one of ordinary skill in the art at the time of the invention, thus entrusting trial courts to interpret claims as a contract or statute?

MAYER, Chief Judge, dissenting.

Until the court is willing to reconsider its holdings in Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff'd on other grounds, 517 U.S. 370 (1996), and Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448

(Fed. Cir. 1998) (en banc), that claim construction is a pure question of law subject to de novo review in this court, any attempt to refine the process is futile. Nearly a decade of confusion has resulted from the fiction that claim construction is a matter of law, when it is obvious that it depends on underlying factual determinations which, like all factual questions if disputed, are the province of the trial court, reviewable on appeal for clear error. To pretend otherwise inspires cynicism. Therefore, and because I am convinced that shuffling our current precedent merely continues a charade, I dissent from the en banc order.

363 F.3d 1207

United States Court of Appeals,
Federal Circuit.

Edward H. PHILLIPS, Plaintiff-Appellant,
v.
AWH CORPORATION, Hopeman Brothers, Inc., and Lofton Corporation, Defendants-Cross-Appellants.

Nos. 03-1269, 03-1286

DECIDED: April 8, 2004.

Carl F. Manthei, Attorney at Law, of Boulder, Colorado, argued for plaintiff-appellant.

Mark W. Fischer, Faegre & Benson LLP, of Boulder, Colorado, argued for defendants-cross appellants. With him on the brief was Scott Holwick.

Before NEWMAN, LOURIE, and DYK, Circuit Judges.

Opinion for the court filed by Circit Judge LOURIE. Opinion dissenting in part filed by Circuit Judge DYK.

LOURIE, Circuit Judge.

Edward Phillips appeals from the decision of the district court granting the defendants' motion for summary judgment of noninfringement of U.S. Patent 4,677,798. *Phillips v. AWH Corp.*, No. 97-MK-212 (D.Colo. Jan. 22, 2003) ("*Noninfringement Decision*"). Phillips also appeals from the dismissal of his claim of trade secret misappropriation. *Phillips v. AWH Corp.*, No. 97-N-212 (D.Colo. Mar. 22, 1999) ("*Trade Secret Misappropriation Decision*"). For the reasons set forth below, we affirm.

BACKGROUND

Phillips is the inventor and owner of the '798 patent, which is directed to vandalism-resistant building modules consisting of modular wall panels. The invention is useful in the field of prison construction because the panels exhibit desirable sound and fire resistance, impact resistance (*i.e.*, against bullets, bombs), and axial and lateral load bearing qualities. A key issue in this case relates to the meaning of the term "baffle." The use of the term "baffle" is typified in Claim 1, which reads as follows:

> Building modules adapted to fit together for construction of fire, sound and impact resistant security barriers and rooms for use in securing records and persons, comprising in combination, an outer shell . . . , sealant means . . . , and *further means disposed inside the shell for increasing its load bearing capacity comprising internal steel baffles extending inwardly from the steel shell walls.*

'798 patent, col. 6, ll. 22-34 (emphasis added).

In 1989, Phillips entered into an agreement with AWH Corporation, Hopeman Brothers, Inc., and Lofton Corporation (collectively "AWH") for AWH to market and sell Phillips' invention. That agreement ended in 1990, and in early 1991, Phillips obtained an AWH sales brochure which convinced him that AWH was continuing to use Phillips' technology without his consent. From January 1991 to June 1992, the parties exchanged letters regarding Phillips' allegations of patent infringement and trade secret misappropriation, but no resolution was ever reached.

On February 3, 1997, Phillips sued AWH in the United States District Court for the District of Colorado, asserting that AWH had misappropriated his trade secrets and had infringed claims 1, 21, 22, 24, 25, and 26 of the '798 patent. In March 1999, the court granted AWH's motion for partial summary judgment that Phillips' claim for trade secret misappropriation was barred by Colorado's three-year statute of limitations, and it dismissed that claim. The court reasoned that Phillips knew or should have known of his alleged injury and failed to exercise due diligence in pursuing his claim of misappropriation. *Trade Secret Misappropriation Decision,* slip op. at 7. The court also decided that Phillips had not presented evidence that AWH engaged in wrongful conduct preventing him from discovering that claim. *Id.* at 7-8.

In November 2002, the district court issued its construction of the '798 patent's claims. *Phillips v. AWH Corp.,* No. 97-MK-212 (D.Colo. Nov. 22, 2002) ("*Claim Construction Order*"). The term "baffle" was of primary importance, and although it was not expressly defined in the written description, the parties stipulated that the term meant a "means for obstructing, impeding, or checking the flow of something." *Id.,* slip op. at 23. In spite of that stipulation, the court concluded that the term was ambiguous because "it does not identify the substance or force the flow of which it is intended to check, impede, or obstruct." *Id.* Although the court acknowledged that "[t]he subject language includes a means and a structure," it decided that the claim language "does not adequately describe the *function* of the structure." *Id.* at 23-24 (emphasis added). The district court therefore concluded that the claim contains means-plus-function language subject

to construction under 35 U.S.C. § 112, ¶ 6 and is limited by the specification. *Id.* at 24.

The court found that the specification referred to properties of sound and heat resistance, as well as fire resistance and projectile deflection. Particularly, the court noted that "every textual reference in the Specification and its diagrams show baffle deployment at an angle other than 90° to the wall faces," and that the figures in the specification all displayed baffles placed in interlocking positions. *Id.* The court therefore concluded that a "baffle," within the context of the '798 patent, has two required properties: first, baffles extend inward from the shell walls at oblique or acute angles; and second, baffles form an intermediate, interlocking barrier in the interior of the wall module. *Id.* at 25.

Phillips conceded that he could not prove infringement under the court's claim construction, and the court granted AWH's motion for summary judgment of noninfringement. *Decision,* slip op. at 1. Phillips timely appeals from both the summary judgment of noninfringement and the dismissal of his trade secret misappropriations claim. AWH cross-appeals, challenging the district court's treatment of certain claim terms in its claim construction. We have jurisdiction over the appeals pursuant to 28 U.S.C. § 1295(a)(1), because a claim of patent infringement was well-pleaded in the complaint. *See Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.,* 535 U.S. 826, 122 S.Ct. 1889, 153 L.Ed.2d 13 (2002). We have pendent jurisdiction over the claim of trade secret misappropriation. *See Roton Barrier, Inc. v. Stanley Works,* 79 F.3d 1112, 1116 (Fed.Cir.1996).

DISCUSSION

We review a district court's grant of summary judgment *de novo,* reapplying the same standard used by the district court. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.,* 149 F.3d 1309, 1315 (Fed.Cir.1998). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c).

I. *Patent Infringement*

Determination of patent infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted . . . , then the properly construed claims are compared to the allegedly infringing device." *Cybor Corp. v. FAS Techs., Inc.,* 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law, *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 970-71 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), that we review *de novo, Cybor,* 138 F.3d at 1456. Step two, comparison of the claim to the accused device or method, requires a determination that every claim limitation or its equivalent is found in the accused device. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). Those determinations are questions of fact. *Bai v. L & L Wings, Inc.,* 160 F.3d 1350, 1353 (Fed.Cir.1998).

On appeal, Phillips argues that the term "baffle" is not in means-plus-function language and should not be limited

to structures described in the specification. Instead, he urges that the "heavy presumption" that "baffle" should be accorded its ordinary and customary meaning was not clearly and unequivocally rebutted. Phillips asserts that the district court improperly read limitations from the specification into the claims – that baffles must be positioned at an acute or obtuse angle to wall faces, and that baffles must form an intermediate, interlocking barrier. Next, for support, Phillips points to descriptions in the '798 patent of baffles that he states are at an angle of 90° to the wall face and of baffles that do not form an interlocking pattern. Finally, Phillips asserts that the district court improperly defined the term "impact resistance" to refer only to deflection of bullets, bombs, or other projectiles. He argues that the term "impact" is used in both the conjunctive and the disjunctive with the term "projectile deflection," which he believes indicates that the term "impact" takes on a broader meaning and that the court's construction was unduly narrow.

AWH responds that the district court correctly construed the term "baffle." The court, AWH argues, properly looked to the specification to determine the scope of the claimed invention. To support the court's construction, AWH emphasizes statements in the '798 patent that purport to distinguish the invention from the prior art, *e.g.*, "impact resistance to great forces such as explosions and projectiles." AWH asserts that the key innovative feature of the invention is the baffle configuration, including both the angled orientation and the interlocking pattern limitations, and that the court was correct to interpret the scope of the claims accordingly. Additionally, AWH argues that the term "impact resistance" is used

throughout the specification with particular reference to bullets, bombs, and other projectiles.

We agree with AWH that the district court ultimately construed the meaning of the term "baffle" properly. Section 112, ¶ 6 provides that:

> an element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112, ¶ 6 (2000). Whether a claim limitation is in means-plus-function format according to 35 U.S.C. § 112, ¶ 6 is a matter of claim construction and thus a question of law that we review *de novo*. *Personalized Media Communications, LLC v. Int'l Trade Comm'n,* 161 F.3d 696, 702 (Fed.Cir.1998). We have held that use of the word "means" creates a presumption that § 112, ¶ 6 applies. *See York Prods., Inc. v. Cent. Tractor,* 99 F.3d 1568, 1574 (Fed.Cir.1996). Conversely, we have also held that the failure to use the word "means" creates a presumption that § 112, ¶ 6 does not apply. *See Mas-Hamilton Group v. LaGard, Inc.,* 156 F.3d 1206, 1213 (Fed.Cir.1998). "In deciding whether either presumption has been rebutted, the focus remains on whether the claim as properly construed recites sufficiently definite structure to avoid the ambit of § 112, ¶ 6." *Personalized Media Communications,* 161 F.3d at 704.

At the outset, we determine that "baffle" is not in means-plus-function language. The claim term in question does not expressly use the word "means,"[1] thereby invoking the presumption that § 112, ¶ 6 does not apply. Moreover, the word "baffle" is a sufficient recitation of structure, which carries its ordinary meaning of "something for deflecting, checking, or otherwise regulating flow." *Webster's Third New International Dictionary* 162 (1993). Its particular structure is not relevant here. Simply because the claims do not identify the matter upon which the baffle acts does not, by itself, rebut that presumption or render the term subject to means-plus-function treatment. Our case law has focused on the structure of claim terms when determining whether § 112, ¶ 6 applies. *See, e.g., Personalized Media Communications,* 161 F.3d at 705 (stating that "an adjectival qualification . . . placed upon otherwise sufficiently definite structure . . . does not make the sufficiency of that structure any less sufficient for purposes of § 112, ¶ 6," but rather "further narrows the scope of those structures covered by the claim and makes the term more definite"). Furthermore, the intrinsic and extrinsic evidence fully and repeatedly support the meaning that baffles check, impede, and obstruct heat, sound, and projectiles such as bullets and bombs. Accordingly, we decide that "baffle" is not means-plus-function language.

However, our analysis does not end there – while the district court erroneously considered the term "baffle" to

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[1] While coincidental, the use of the word "means" in the stipulated definition of "baffle" does not automatically invoke means-plus-function treatment. The district court was not baffled by that usage and was correct not to rely on that word in its reasoning.

be in means-plus-function format, we must still read the claims in view of the specification and determine whether the patentee has otherwise limited the scope of the claims with respect to the term "baffle." The ordinary meaning of a term must be considered in view of the intrinsic evidence: the claims, the specification, and the prosecution history. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342-43 (Fed.Cir.2001). "[A] claim term will not carry its ordinary meaning if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed.Cir.2002). Thus, we look to the specification "to ascertain the meaning of a claim term as it is used by the inventor in the context of the entirety of his invention." *Comark Communications v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed.Cir.1998).

The '798 patent specification is rife with references to impact resistance, especially against projectiles such as bullets and bombs. The abstract describes the invention as "[v]andalism resistant building modules . . . [that] provide . . . significant resistance to noise, fire and impact" and specifically states that "[t]he modules contain strengthening and bullet deflecting internally directed steel baffles." It further explains that steel panels "form the internal baffles at angles for deflecting bullets." In the section marked "Disclosure of the Invention," the patentee states that the baffles are "disposed at such angles that bullets which might penetrate the outer steel panels are deflected." '798 patent, col. 2, ll. 13-15.

Additionally, the specification addresses and distinguishes the prior art, asserting that "[i]n secured facilities,

and protective barriers, it is feasible that projectiles may be encountered, such as bullets from high powered guns or bomb fragments." *Id.* at col. 3, ll. 26-28. It continues by stating that "[t]here have not been effective ways of dealing with these powerful impact weapons with inexpensive housing in the prior art." *Id.* at col. 3, ll. 28-31.

The specification further contains a Figure 6, explaining that if bullets "were to penetrate the outer steel shell wall, the baffles are disposed at angles which tend to deflect the bullets." *Id.* at col. 5, ll. 17-19. Figure 12 is also shows that "[t]ypical wall characteristics include bullet and explosion resistance." *Id.* at col. 5, ll. 67-68. Finally, the patentee concludes that the "invention has advanced the art by providing modular buildings and modules of high strength [and] bullet resistance," adding that "[u]niquely the advantages of steel shell modules are combined with thermal and acoustical isolation of two spaced walls and protection against *bullet penetration of the walls.*" *Id.* at col. 6, ll. 10-17 (emphasis added).

We are not persuaded by Phillips' arguments that the specification also contains descriptions of baffles that are 90° to the wall face. To support his assertion, Phillips points to segments of baffles in Figure 7 as oriented perpendicular to the walls. However, those segments merely support the predominant angled portions that impart the bullet deflection properties that Phillips identifies as essential to his invention and are not identified as baffles.

From the specification's explicit descriptions of the invention, we conclude that the patentee regarded his invention as panels providing impact or projectile resistance and that the baffles must be oriented at angles other

than 90°. Baffles directed at 90° cannot deflect projectiles as described in the '798 patent, and, in any event, are disclosed in the prior art. *See, e.g.,* U.S. Patents 2,717,664 and 4,505,101. The term "baffle" is used in a consistent manner throughout all the asserted claims, so our foregoing analysis applies equally to all those claims. Because we so construe the '798 patent, and because AWH does not use acute or obtuse angles in its panels, we affirm the district court's judgment of noninfringement.

The dissent-in-part argues that we have interpreted the claims erroneously by focusing only on the "preferred embodiment." We disagree. Inspection of the patent shows that baffles angled at other than 90° is the *only* embodiment disclosed in the patent; it is the invention. It is impossible to derive anything else from the specification.

The specification indicates at column 1, line 65 to column 2, line 15 under DISCLOSURE OF THE INVENTION that

> This invention provides modular equipment for formulating detention structures comprising of [sic] a multiplicity of interchangeable modules of similar size having steel plate inner and outer wall sections defining end closures and internally directed load supporting baffles. The modules comprise three steel plate wall panel sections of partially triangular cross section shape positioned to provide the internally directed baffles. . . .
>
> The baffles provided by the triangular shaped panels to extend inwardly from an intermediate interlocking barrier with the baffles disposed at such angles that bullets which might penetrate the outer steel panels are deflected.

The only actual references to baffles in the specification are to numbers 16, 26, 27, 30, 31, all of which are angled in the figures of the patent. It further states at column 5, lines 5-19: "*The* additional feature of this module is that it gives additional protection against projectile penetration. Thus it may been seen from FIG. 6 that if a bullet were to penetrate the outer steel shell wall, the bullets are disposed at angles which tend to deflect the bullets." (Emphasis added.) None of the figures shows any baffle that is not angled at an angle other than 90°.

It is true that claims with the non-restrictive term "baffles" were allowed. However, the patent specification is intended to support and inform the claims, and here it makes it unmistakably clear that the invention involves baffles angled at other than 90°. It is in the interests of a sound patent system and inventors, as well as the public, to hold inventors to their disclosures. The trial judge correctly perceived this need, albeit mistakenly relying on the means-plus-function ground, and interpreted the claims in accordance with the specification.

II. *Misappropriation of Trade Secrets*

The district court dismissed the plaintiff's claim of misappropriation of trade secrets on a statute of limitations ground. We agree with the court's decision on that basis. Federal courts apply the trade secret law of the state in which they sit. *See Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 670 (Fed.Cir.1988); *Sun Studs, Inc. v. Applied Theory Assocs., Inc.*, 772 F.2d 1557, 1561 (Fed.Cir.1985). The Colorado Uniform Trade Secrets Act ("CUTSA"), Colo.Rev.Stat. §§ 7-74-101 to -110 (1998), applies to claims of trade secret misappropriation brought under Colorado

law, including those in federal courts. *Gates Rubber Co. v. Bando Chem. Indus., Ltd.,* 9 F.3d 823, 847 (10th Cir.1993). Here, there is no dispute between the parties that Colorado trade secret law controls. The district court's interpretation of Colorado trade secret law is a matter of law that we review de novo. *See Salve Regina Coll. v. Russell,* 499 U.S. 225, 231, 111 S.Ct. 1217, 113 L.Ed.2d 190 (1991).

Colorado state law provides a three-year statute of limitations period for claims of trade secret misappropriation.

> An action for misappropriation of a trade secret shall be brought within three years after the misappropriation is discovered or by the exercise of reasonable diligence should have been discovered. For purposes of this section, a continuing misappropriation constitutes a single claim.

Colo.Rev.Stat. § 7-74-107 (1998). The Colorado Supreme Court has stated, with respect to actions in tort, that "[t]he statute of limitations begins to run when the claimant has knowledge of facts which would put a reasonable person on notice of the nature and extent of an injury and that the injury was caused by the wrongful conduct of another." *Mastro v. Brodie,* 682 P.2d 1162, 1168 (Colo.1984). "[T]he cause of action does not accrue until the plaintiff knows, or has reason to know, in the exercise of reasonable diligence, all material facts essential to show elements of that cause of action." *City of Aurora v. Bechtel Corp.,* 599 F.2d 382, 389 (10th Cir.1979).

Phillips argues that he did not "discover" AWH's alleged misappropriation until August 1996 so that the three-year statute of limitations did not expire before he filed the lawsuit. He asserts that the 1991 and 1992

correspondence lacked particular details of AWH's alleged use of Phillips' technology and that Phillips was unable to discern the true nature of his injury. Phillips advances the argument that accrual of the tort of trade secret misappropriation under Colorado law occurs only when both the injury and its cause are known. Because he did not know of AWH sales of the accused technology until August 1996, Phillips alleges that he could not determine recoverable damages and that his claim was incomplete. Moreover, Phillips raises equitable tolling arguments based on mental disability and AWH's assurances that it was not using Phillips' technology.

In response, AWH highlights the strong, specific language Phillips used in his 1991 and 1992 letters, all of which indicate that his awareness of possible trade secret misappropriation had risen well above mere suspicion. AWH argues that in his letters, Phillips indicated with particularity the technology that he believed AWH was misappropriating, citing the AWH sales brochure that Phillips had in his possession. The appellees further assert that under Colorado state law, mental disability must exist at the time such right accrues for equitable tolling to operate. AWH states that its assurances to Phillips amounted to mere denial of liability and not wrongful conduct implicating the doctrine of equitable tolling.

We agree with the district court that Phillips' claim of trade secret misappropriation is time-barred by Colorado state law. Phillips possessed an AWH sales brochure that detailed the companies' alleged use of his technology and prompted correspondence between the parties. In his letters to AWH, Phillips referred to the brochure's contents, identified specific technology that he believed was being used without his permission, and detailed an explicit

timeline of events leading to AWH's alleged misappropriation. Phillips even used terms such as "steal" and "misappropriated," indicating that he was very much aware of AWH's actions, how they related to his technology, and how they affected his own interests, financial or otherwise. Phillips' possession of the AWH brochure and his letters convincingly indicate that Phillips knew or should have known facts sufficient to support his claim of misappropriation. That Phillips was not aware of the particular use of his technology, of AWH's specific sales, or of the exact monetary damage inflicted is not of consequence. One does not need to know the specific damage inflicted in order to bring a claim. *See* Colo.Rev.Stat. § 7-74-107 (1998); *Gates Rubber Co.,* 9 F.3d at 847. As a result, we conclude that Phillips' claim for trade secret misappropriation accrued prior to the critical date, February 3, 1994 – three years before the commencement of suit in the district court, and hence out of time.

As for Phillips' equitable tolling arguments, we are not convinced that his alleged mental disability warrants exercise of the doctrine of equitable tolling because it did not exist when Phillips discovered the alleged misappropriation. *See* Colo.Rev.Stat. § 13-81-103 (2002). Furthermore, courts interpreting Colorado law have held that "[t]he mere denial of liability, which is what an assertion of independent development amounts to in the face of a trade secret misappropriation claim, is not 'wrongful conduct' which implicates the doctrine of equitable tolling." *Chasteen v. UNISIA JECS Corp.,* 216 F.3d 1212, 1221 (10th Cir.2000) (citing *Dean Witter Reynolds, Inc. v. Hartman,* 911 P.2d 1094, 1096 (Colo.1996)). We therefore conclude that equitable tolling does not apply and that Phillips' claim of

trade secret misappropriation is barred by Colorado's statute of limitations.

III. *Cross-Appeal*

AWH disputes several additional claim terms in its cross-appeal. We dismiss the cross-appeal as improper because the district court entered a judgment of noninfringement in favor of AWH. A party has no right of cross-appeal from a decision in its favor. *Lindheimer v. Ill. Bell Tel. Co.*, 292 U.S. 151, 176, 54 S.Ct. 658, 78 L.Ed. 1182 (1934). Similarly, a party who prevails on noninfringement has no right to file a "conditional" cross-appeal to introduce new arguments or challenge a claim construction, but may simply assert alternative grounds in the record for affirming the judgment. *Bailey v. Dart Container Corp. of Mich.*, 292 F.3d 1360 (Fed.Cir.2002); *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 822 n. 1 (Fed.Cir.1989).

CONCLUSION

We have considered Phillips' remaining arguments and find them unpersuasive. We therefore conclude that the district court properly granted summary judgment in favor of AWH on Phillips' patent infringement and trade secret misappropriation claims, and we accordingly affirm. We dismiss AWH's cross appeal as improper and, in any event, moot.

AFFIRMED.

DYK, Circuit Judge, dissenting-in-part.

I respectfully dissent from the majority's affirmance of the district court's judgment of non-infringement. The

majority decision effectively limits the claims to the preferred embodiment, contrary to our recent decision in *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed.Cir.2004), and numerous other decisions of this court. In doing so, the majority decision attempts to work a major and unfortunate change in our recent claim construction jurisprudence.

The issue here is the meaning of the claim term "baffles," which appears in each of the asserted claims of the '798 patent. I agree that "baffles" is not a means-plus-function term because, as the majority notes, "the word 'baffle' is a sufficient recitation of structure." *Ante* at 1212. There is no dispute as to the plain meaning of the term "baffles." The parties have stipulated that "baffles" are a "means for obstructing, impeding, or checking the flow of something." *Phillips v. AWH Corp.*, No. 97-MK-212, slip op. at 23 (D.Colo. Nov. 22, 2002); *see also Webster's Third New International Dictionary* 162 (2002) ("*Webster's*") (defining baffles as "something for deflecting, checking, or otherwise regulating flow"). Indeed, the majority agrees that this is the "ordinary meaning." *Ante* at 1212.

My dispute is with the majority's imposition of an additional structural limitation based upon the patentee's preferred embodiments that limits baffles to structures "oriented at angles other than 90°." *Ante* at 1213. This is contrary to the plain meaning, and there is no suggestion that the patentee, acting as his own lexicographer, gave a special meaning to the term baffles. The majority marshals three arguments in support of limiting the claims to baffles oriented at angles other than 90°. None is convincing.

First, the majority concludes that baffles must be limited to structures oriented at angles other than 90° because "the patentee regarded his invention" as such, *ante* at 1212-13, describing only such baffles in the specification. It states that "baffles angled at other than 90° is the *only* embodiment disclosed in the patent; it is the invention." *Ante* at 1213. We however have "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Liebel-Flarsheim,* 358 F.3d at 906.

Our precedent also makes clear that "this court interpret[s] the pertinent claim language narrowly, not merely because the specification d[oes] not describe a broader embodiment, but because the specification, claim, or prosecution history ma[kes] clear that the invention is limited to a particular structure." *Liebel-Flarsheim,* 358 F.3d at 907-08. As in *Liebel-Flarsheim,* the specification here does "not suggest that [baffles oriented at angles other than 90°] are an essential component of the invention, nor is there any language . . . in the specification, that disclaims the use of the invention in the absence of [baffles oriented at angles other than 90°]." *Id.* at 908; *see also Sunrace Roots Enter. Co. v. SRAM Corp.,* 336 F.3d 1298, 1305 (Fed.Cir.2003). Nor is this a case like *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.,* 242 F.3d 1337 (Fed.Cir.2001), where the specification specifically disclaimed non-disclosed embodiments by stating that the "structure defined above is the basic . . . structure for *all embodiments of the present invention contemplated and disclosed herein.*" *Id.* at 1343 (quoting the patents at issue). The specification of the '798 patent

contains no such language clearly limiting the claims to a specific structure.

Second, the majority contends that the baffles must be limited to structures oriented at angles other than 90° in order to realize the invention's *purpose* of providing panels that are impact or projectile resistant. The theory for this departure from the broader plain meaning is that "[b]affles directed at 90° cannot deflect projectiles as described in the '798 patent," *ante* at 1213, and projectile deflection is critical because the "specification is rife with references to impact resistance, especially against projectiles such as bullets and bombs," *ante* at 1212. The specification however merely identifies impact resistance as one of several objectives of the invention. The patent also identifies other objectives including "high load bearing strength" using "thinner guage [sic] steel panels," '798 patent, col. 3, ll.16-25, and "thermal and acoustical isolation of two spaced walls," *id.* at col. 6, l.16.[2] As we made clear in *Liebel-Flarsheim,* "[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." 358 F.3d at 908; *see also E-Pass Techs., Inc. v. 3Com Corp.,* 343 F.3d 1364, 1370 (Fed.Cir.2003). So too, "[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that

[2] This "thermal and acoustical isolation" refers to the lack of a continuous link across the interior of the panels. Since the baffles on each side of the panel's interior do not physically touch, the flow of sound and heat from one side to the other is restricted.

context." *Liebel-Flarsheim,* 358 F.3d at 909 (quoting *Northrop Grumman Corp. v. Intel Corp.,* 325 F.3d 1346, 1355 (Fed.Cir.2003)) (alteration in original). Here baffles that are oriented at 90°, and thus excluded under the majority's construction, would still achieve the load bearing and thermal-acoustical isolation objectives taught in the specification. The identification of an objective that is not met when the claim is given its ordinary meaning is not in itself a disclaimer sufficient to narrow that ordinary meaning. This is particularly so here where impact or projectile resistance is separately identified as a claim limitation in claims 1-21, 23 and 24, thereby suggesting that the baffles and impact resistance limitations are separate.

Finally, the majority relies on the fact that "[b]affles directed at 90° . . . in any event, are disclosed in the prior art," *ante* at 1213, perhaps suggesting that the claim would be invalid if given a broader meaning. But the fact that a feature of the invention may have been described in the prior art hardly raises serious questions of invalidity. *See, e.g., Schering Corp. v. Geneva Pharms., Inc.,* 339 F.3d 1373, 1377 (Fed.Cir.2003) ("[A]nticipation [occurs] if a single prior art reference discloses *each and every* limitation of the claimed invention." (emphasis added)). Even if there were such questions, this also is no excuse to depart from the plain meaning of the claims. The "axiom" that claims should be construed to preserve validity is not an invitation to narrowly construe unambiguous claim language contrary to its plain meaning. *See, e.g., Liebel-Flarsheim,* 358 F.3d at 911; *Elekta Instrument S.A. v. O.U.R. Scientific Intl., Inc.,* 214 F.3d 1302, 1309 (Fed.Cir. 2000). Nor, was there here an effort to distinguish the

prior art on the basis that prior art baffles were oriented at 90° angles. *See SciMed,* 242 F.3d at 1343.

Simply put, there is no reason to supplement the plain meaning of the claim language with a limitation from the preferred embodiment. By limiting "baffles" to structures "oriented at angles other than 90°," *ante* at 1213, the majority has misconstrued not only the claims, but our precedent as well. Limiting the claims to the preferred embodiment as the majority has done is quite inconsistent with our cases which consistently reject the notion that the claims are limited to the preferred embodiment. *Liebel-Flarsheim,* 358 F.3d at 906, *see also, e.g., ACTV, Inc. v. Walt Disney Co.,* 346 F.3d 1082, 1091 (Fed.Cir.2003); *E-Pass,* 343 F.3d at 1369; *Apex Inc. v. Raritan Computer, Inc.,* 325 F.3d 1364, 1373 (Fed.Cir.2003); *Teleflex, Inc. v. Ficosa N. Am. Corp.,* 299 F.3d 1313, 1327 (Fed.Cir.2002).

II

Discarding the majority's approach of limiting the claims to the preferred embodiment, the question remains as to the correct construction of the claims. Since there is no argument here that one of skill in the art would ascribe a specialized meaning to the term baffles, and there has been no disclaimer in the specification or prosecution history, the general purpose dictionary definition, "something for deflecting, checking, or otherwise regulating flow," *Webster's* at 162, applies. *See Texas Digital Sys., Inc. v. Telegenix, Inc.,* 308 F.3d 1193, 1203-04 (Fed.Cir.2002); *see also, e.g., Kumar v. Ovonic Battery Co.,* 351 F.3d 1364, 1367 (Fed.Cir.2003); *E-Pass Techs.,* 343 F.3d at 1367-68.

The district court's grant of summary judgment should be vacated because it was based solely on the

erroneous construction of baffles and the patentee's concession that the accused product did not contain baffles as so defined. I do not reach the district court's construction of other claim terms or the question of whether summary judgment of non-infringement could or should be granted on other grounds. I agree with the majority opinion on the trade secret claim.

03-1082, -1165

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

LIEBEL-FLARSHEIM COMPANY and MALLINCKRODT, INC.,

Plaintiffs-Appellants,

v.

MEDRAD, INC.,

Defendant-Cross-Appellant.

Appeal from the United States District Court For the Southern District of Ohio in Case No. C-1-98-859, Judge Sandra S. Beckwith

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DEFENDANT-CROSS-APPELLANT MEDRAD, INC.'S COMBINED PETITION FOR PANEL REHEARING AND PETITION FOR REHEARING EN BANC

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February 25, 2004

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* * *

CERTIFICATE REQUIRED BY RULE 35(B)

Based on my professional judgment, I believe the Panel decision is contrary to the following decision(s) of the Supreme Court of the United States or the precedent(s) of this Court:

Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996)

Microsoft Corp. v. Multi-Tech Systems, Inc., 2004 WL 191013 (Fed. Cir. Feb. 3, 2004)

Biogen, Inc. v. Berlex Labs, Inc., 318 F.3d 1132 (Fed. Cir. 2003)

Cultor Corp. v. A. E. Staley Mfg. Co., 224 F.3d 1328 (Fed. Cir. 2000)

Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377 (Fed. Cir. 1999)

Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973 (Fed. Cir. 1999)

Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (1996)

Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)

Teleflex, Inc. v. Ficosa North American Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002)

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent setting questions of exceptional importance:

1. What is the proper claim construction analysis for patents that disclose a single embodiment but contain

claim language that can be interpreted more broadly in the abstract: (1) the "manifest exclusion" analysis used by this Panel and based on *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002); or (2) the specification and prosecution history-based analysis used in *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 2004 WL 191013, *5 (Fed. Cir. Feb. 3, 2004) and *Wang Laboratories, Inc. v. America On-Line, Inc.*, 197 F.3d 1377, 1383-84 (Fed. Cir. 1999)?

2. Whether the "manifest exclusion" claim construction axiom set forth in *Teleflex*, and adopted by the Panel here applies to expand a claim to cover an embodiment that was: (1) not disclosed in the specification; (2) not known in the prior art at the time the specification was filed; *and* (3) thus, could not have been the subject of a "manifest exclusion or restriction?"

3. Whether extrinsic evidence of the patentee's subjective intentions is admissible to broaden the construction of a claim, even though: (1) the intrinsic prosecution history contradicts that intention to claim; (2) the specification includes no disclosure regarding or supporting that intention to claim; *and* (3) the extrinsic evidence did not exist and could not have existed at the time the original disclosure was filed?

4. Whether the removal, without any reservation, of an explicit claim limitation contained in every claim filed with a parent application, followed by the addition of that limitation back into every claim in an amendment to "clarify the inventive concepts claimed," *limits* the construction of a claim in subsequent continuation and divisional applications?

5. Whether the public notice function of a patent is properly served when patent claims are construed to cover an embodiment that *was not*: (1) disclosed in the patent specification; (2) described in the prior art; (3) reduced to practice by the applicant; *and* (4) even considered to be patentable by the applicant?

/s/ Frederick H. Colen
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(6)

No. 04-32

Supreme Court, U.S.
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In The

Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

SUPPLEMENTAL BRIEF RELATING TO NEW AUTHORITY IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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SUPPLEMENTAL BRIEF

Pursuant to Supreme Court Rule 15.8, Petitioner Medrad, Inc. respectfully submits the following new authority in support of its Petition for Certiorari. Attached as an appendix (App. 170-95) to this submission is the amicus brief of the United States, represented by the United States Patent and Trademark Office, the Department of Justice and the Federal Trade Commission, filed in *Phillips v. AWH Corp. et al.*, Fed. Cir. Appeal Nos. 03-1269, -1286, an *en banc* proceeding in the Federal Circuit. This brief was not available to Medrad at the time of its last brief filed in this Court. *See* Sup. Ct. R. 15.8.

The parallels between the claim construction issues raised in *Phillips* and those raised in Medrad's certiorari petition previously have been noted in Medrad's Supplemental Brief Relating To New Developments In The Federal Circuit In Support Of Petition For Writ Of Certiorari filed in this Court on August 5, 2004. Of particular note, Medrad emphasized why the overlap between these respective cases supported either: (1) a grant of Medrad's petition with a remand to the Federal Circuit for decision in light of the result in *Phillips*; or (2) a grant of Medrad's petition and stay of the proceedings in this Court pending resolution in *Phillips*.

The attached amicus brief filed by the United States supports Medrad's views on the nature and significance of the disputed claim construction issues, the correct methodology for construing patent claims, and underscores the propriety of the specific relief Medrad seeks in this Court. (App. 170-95). The United States' amicus brief makes clear why the result reached by the Federal Circuit in this case is erroneous and warrants further appellate review. The

brief also highlights that important governmental interests are at stake in this proceeding and the views of the federal government align with a grant of certiorari in this case.

Medrad accordingly submits the attached amicus brief of the United States in support of the relief requested in Medrad's Petition for Certiorari and Supplemental Brief filed with this Court.

DATED: September 27, 2004

Respectfully submitted,

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BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE*

United States Court of Appeals
For the Federal Circuit

Appeal Nos. 03-1269, -1286

EDWARD H. PHILLIPS
Plaintiff-Appellant
v.
AWH CORPORATION, HOPEMAN BROTHERS, INC. AND LOFTON CORPORATION
Defendants-Cross Appellants

Appeal from the United States District Court for the District of Colorado, Case No. 97-MK-212 (CBS)
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September 20, 2004

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OTHER AUTHORITIES

Joseph Scott Miller & James A. Hilsenteger, The Proven Key: Roles and Rules for Dictionaries at the Patent Office and the Courts, (unpublished manuscript, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=577262) 22

R. Polk Wagner & Lee Petherbridge, Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance, 152 U. Pa. L. Rev. 1105 (2004) ... 21-22

BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE*

United States Court of Appeals
For the Federal Circuit

Appeal Nos. 03-1269, -1286

EDWARD H. PHILLIPS
Plaintiff-Appellant
v.
AWH CORPORATION, HOPEMAN BROTHERS, INC. AND LOFTON CORPORATION
Defendants-Cross Appellants

Appeal from the United States District Court for the District of Colorado, Case No. 97-MK-212 (CBS)
Judge Marcia S. Krieger

INTRODUCTION

In response to the July 21, 2004 Order from the Court, the United States Patent and Trademark Office

("USPTO"), with the support of United States Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), respectfully submits this *amicus curiae* brief. See also Fed. R. App. P. 29.

STATEMENT OF INTEREST

The United States' strong interest in a fair, stable, predictable, and efficient patent system embraces a number of perspectives, including: (i) the USPTO's responsibility for examining all patent applications, and construing the claims therein; (ii) DOJ's and the FTC's interest in advancing consumer welfare through enforcement of competition laws and advocacy on competition-related issues; (iii) as a patent holder; and (iv) as a defendant in patent infringement actions.

ISSUES PRESENTED

The Court's July 21, 2004 Order sets out seven questions. They generally fall under three broad categories: (1) how and to what extent various types of evidence, particularly the specification and dictionaries, should be relied on for claim construction; (2) how the specification should properly be used to interpret claims without impermissibly importing limitations into the claims; and (3) what deference, if any, this Court should give a district court's claim construction.[1]

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[1] The government takes no position on the specific facts of this case.

ARGUMENT

I. *Introduction and Background* – *Overview of* Claim Construction Precedent and Policy

Claim construction necessitates balancing the public notice function of patents with the sometimes competing policy of a fair scope of protection for patentees. As the Supreme Court noted, "[i]t seems to us that nothing can be more just and fair, both to the patentee and to the public, than that the former should understand, and correctly describe, just what he has invented, and for what he claims a patent." *Merrill v. Yeomans*, 94 U.S. 568, 573-74 (1876).

Ideally, the patentee's correct description of the invention should be clearly reflected in the claims. Yet patent infringement and invalidity cases routinely involve disputes over the meaning of claim language. Principles of claim construction that stress the understanding of persons of ordinary skill in the art facilitate equitable treatment of patentees and the public, and should produce predictability in claim interpretation.

A. *Markman* and *Cybor*: Claim Interpretation as a Legal Issue Subject to *De Novo* Review

Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) affirmed this Court's *en banc* holding that no jury right exists for claim interpretation. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*). Subsequently, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (*en banc*) held that the meaning of any given word in a claim constitutes a pure question of law, reviewed *de novo* on appeal. However, five concurring and dissenting judges stated that some form of

deference should be given to the district courts' claim interpretation. *Id.*

B. *Vitronics:* Preferred Claim Construction Evidence and Methodology

This Court provided significant guidance on claim construction methodology in *Vitronics v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996). Giving primacy to intrinsic evidence of record (the claims, specification, prosecution history and cited prior art) over extrinsic evidence (*e.g.*, expert testimony, treatises, dictionaries), the Court deemed it improper to rely on extrinsic evidence if the intrinsic evidence provided sufficient clarity. *Id.* at 1582-83. However, in the event of an ambiguity, extrinsic evidence may be permitted "to help the court come to the proper understanding of the claim term," but not to contradict intrinsic evidence or to vary the scope of the claims. *Id.* at 1584. Also *Vitronics* noted that among the types of extrinsic evidence, "prior art documents and dictionaries, although to a lesser extent, are more objective and reliable guides" than expert testimony, which tends to be biased. *Id.* at 1585.

C. *Texas Digital:* Heightened Reliance on Dictionaries

Texas Digital Systems. Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002) seemed to contradict some of the holdings of *Vitronics*, and elevated the importance of dictionaries. The *Texas Digital* court opined that routinely looking to dictionary definitions first, as the baseline for a claim construction analysis, would help avoid improper importation of limitations from the specification and

further the goal of giving claim terms their "ordinary and customary" meaning. *Id.* at 1202. In particular, the decision stated that dictionaries and treatises "may be the *most meaningful* sources of information to aid judges in better understanding both the technology and the terminology used by those skilled in the art to describe the technology." *Id.* at 1203 (emphasis added).

Texas Digital suggested starting with dictionaries, and then looking to the intrinsic record only to determine whether the dictionary definition is rebutted. *Id.* at 1204. The Court indicated that dictionary evidence establishes a "heavy presumption," requiring a court to give the term "the full range of its ordinary meaning" according to the dictionary, unless "compelled otherwise." *Id.* at 1203. According to *Texas Digital*, a court may depart from the dictionary definition in two limited circumstances: (i) lexicography, when the specification sets forth an explicit definition of the term different from its ordinary meaning, or (ii) disclaimer, when the specification "us[es] words or expressions of *manifest exclusion or restriction*, representing a clear disavowal of claim scope." *Id.* at 1204 (emphasis added). However, this Court's recent precedent reflects that these two circumstances, where the specification explicitly "trumps" the dictionary, rarely arise.

D. Post-Texas *Digital:* The Current, Conflicting State of the Law on Claim Construction

Texas Digital set the stage for a much more ubiquitous and prominent role for dictionaries in claim construction, in the hope that the objectivity of dictionary definitions would alleviate many of the difficulties with claim construction. However, this laudable goal has not been realized.

Litigants have converted claim construction disputes into a "battle of the dictionaries." The increased reliance on dictionary definitions as a foundation for claim meaning has generated inconsistent and unpredictable results, and therefore has not improved the state of the law of claim construction. In some instances, beginning with a dictionary definition has resulted in a broadening of claims beyond what the public record likely reflects to a person of ordinary skill in the art. In *Nystrom v. Trex Co.*, 374 F.3d 1105, 1106 (Fed. Cir. 2004), the majority interpreted the term "board" to cover not only wood, but any hard surface, even though, as the dissent noted, it is unclear that the specification would support such a broad definition.[2] In other instances, with multiple dictionaries in play, the Court selected a narrower definition. For example, *Intellectual Property Dev., Inc. v. UA-Columbia Cablevision of Westchester, Inc.*, 336 F.3d 1308, 1315-16 (Fed. Cir. 2003) adopted a more restrictive definition of "high frequency" common to *all* the dictionary sources consulted, and rejected the contention that looking at the dictionary before the intrinsic evidence "put the cart before the horse."

Resorting to different dictionaries from case to case has undermined the clarity and predictability that *Texas Digital* sought, because the uncertainty about which dictionary the Court will use prevents patent applicants from adjusting their expectations around a particular,

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[2] This desire to give claims a broad literal scope may be the result of the restrictions placed on the availability of the doctrine of equivalents by the recent decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002), and on remand, 344 F.3d 1359 (Fed. Cir. 2003) (*en banc*).

designated dictionary. For instance, in *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363 (Fed. Cir. 2004), the district court relied on *Webster's Ninth New Collegiate Dictionary*, but this Court relied instead on *Webster's Third New International Dictionary*, and reversed the district court's construction of one term based on a usage note from *Webster's Third*. In *TI Group Automotive Systems, Inc. v. VDO North America LLC*, 375 F.3d 1126 (Fed. Cir. 2004), this Court relied in part on the *Oxford English Dictionary*, while in *Anchor Wall Systems, Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1311 (Fed. Cir. 2003), this Court turned to *Webster's Third*, although the district court had relied on *Merriam-Webster Collegiate Dictionary*.

Moreover, the lack of clarity as to which dictionary to use is further complicated by the lack of clarity as to *which definition within a particular dictionary* to use. *See Nystrom*, 374 F.3d at 1112 (relying on the second of two definitions of "board" found in *The American Heritage Dictionary*). Another growing phenomenon is the use of dictionaries sequentially to define term after term. For example, in *Novartis Pharmaceuticals Corp. v. Eon Labs Mfg.*, 363 F.3d 1306, 1308-10 (Fed. Cir. 2004), the Court divided the term "hydrosol" into its component terms, consulted dictionary entries first for those terms, then again for other terms in the dictionary entries. Thus, even with an established approach of turning first to dictionary evidence, the interested parties cannot anticipate which sources or definitions will determine claim meaning, or which terms within a definition the court might decide require further definition.

More fundamentally, the use of dictionaries as the initial baseline for the meaning of claim language, instead of the intrinsic evidence, runs counter to the long-established

doctrine that claims should be understood in view of the specification as a whole. "[I]t is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention." *United States v. Adams*, 383 U.S. 39, 48-49 (1966). Primary reliance on dictionaries that are not part of the patent's public record subordinates the patentee's own explanation of his invention in favor of a dictionary definition never at issue during the patent prosecution before the USPTO.

II. Claim Construction Should Start with the Intrinsic Evidence

A. Intrinsic Evidence

Our first issue – how and to what extent various types of evidence should be relied on in claim construction – relates to questions (1) through (4) and (6). As *Vitronics* stated, reliance on the intrinsic evidence as the starting point for interpreting claims preserves established doctrines of patent law, does not upset settled expectations, and achieves a reading of patent claims that serves the public notice function of claiming while remaining fair to the patentee. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582 (citations omitted).

Moreover, primary reliance on intrinsic evidence, rather than later-determined dictionaries that were not

part of the record, generates the greatest likelihood that the claim construction will be consistent with the USPTO's interpretation of the claims in issuing the patent.[3] While patent examiners and prosecutors may frequently rely on their own understanding of terms, both technical and non-technical, they rarely, if ever, explicitly rely on dictionary definitions to understand or define claim terms.

Using the dictionary as the premise, and looking to the specification only for rebuttal by lexicography or clear disclaimer/disvowal is a problematic approach. Specifically, the patentee and the USPTO typically focus on the "context" of the invention as reflected in the specification rather than on dictionary evidence. *See White v. Dunbar*, 119 U.S. 47, 51 (1886) ("The context may, undoubtedly, be resorted to, and often is resorted to, for the purpose of better understanding the meaning of the claim"). The

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[3] The USPTO employs an approach to claim construction somewhat distinct from a district court's approach. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997) (noting USPTO's and courts' different claim construction approaches, in view of their different roles). During prosecution, claims are "given their *broadest reasonable interpretation* consistent with the specification. . . . Giving claims their broadest reasonable construction 'serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified.'" *In re Am. Academy of Sciences*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (emphasis added) (citations omitted); see *also In re Bigio*, No. 03-1338, ___ F.3d ___ (Fed. Cir. 2004). The policy underlying USPTO's "broadest reasonable interpretation" approach stems from the applicant's opportunity during patent prosecution to amend the claims. *See id.*; *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

The USPTO may not have understood the claim term in the broadest sense *possible*, but rather in the broadest *reasonable* sense, informed by the specification, cited prior art and arguments by the applicant. For courts not to give primacy to the context provided by the intrinsic evidence therefore risks interpretation of claims at odds with the USPTO's interpretation in issuing the patent.

USPTO examines applications according to the principle set out in Rule 1.75(d)(1) that "[t]he claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description *so that the meaning of the terms in the claims may be ascertainable by reference to the description.*" 37 C.F.R. § 1.175(d)(1) (emphasis added). Use of later-selected extrinsic dictionary evidence "might in some instances unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such a presumption would apply" who, "[y]ears after the fact, . . . may find it difficult to establish an evidentiary basis that would overcome the new presumption." *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 41 (1997) (Ginsburg, J., concurring). Given the effort to make the significance of claim terms transparent from the specification, the public and the courts should logically first turn to the specification, which *was* considered during prosecution, to help understand the scope of the claimed invention.

The government maintains that the specification and prosecution history should receive more extensive consideration in claim construction than merely to rebut a dictionary either by lexicography or clear disclaimer, two relatively rare occurrences. The intrinsic evidence, including cited prior art, may indirectly convey the customary meaning of a disputed claim term, or will at least provide additional useful context that should be considered when consulting extrinsic evidence. In such cases, while lexicography does not explicitly define claim terms, " 'the specification may still define [them] 'by implication' such that the meaning may be found or ascertained by a reading of the

patent documents.'" *Novartis Pharmaceuticals Corp v. Abbott Labs.*, 375 F.3d 1328, 1334 (Fed. Cir. 2004) (citations omitted). In *Vanderlande Ind. v. ITC*, 366 F.3d 1311, 1318 (Fed. Cir. 2004), this Court noted that the specification should first be consulted to determine if claim terms are expressly or *impliedly* defined. For example, where a claim term by itself might have several possible ordinary meanings, the specification or prosecution history may indicate the most appropriate definition, by context and implication. This Court has correctly observed that the use of "a claim term throughout the entire patent specification, in a manner consistent with a single meaning" may define that term "by implication." *Bell Atlantic Network Services, Inc. v. Covad Communications Group*, 262 F.3d 1258, 1271 (Fed. Cir. 2001). Thus, in selecting among several possible ordinary meanings, one meaning may be inferred from the patent specification's use of the term throughout in a manner consistent with that particular meaning of the term.

B. Extrinsic Evidence, Including Dictionaries

Claims must be construed from the perspective of one of ordinary skill in the art, and a judge attempts to replicate that perspective in reviewing the intrinsic evidence. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003) ("The words used in the claims are examined through the viewing glass of a person skilled in the art"). Thus, the courts may turn to extrinsic evidence to aid in finding the level of ordinary skill in the art, in understanding the intrinsic evidence, and in discerning the meaning that one skilled in the art would give claim terms when read in the context of the entire specification. A judge may consider extrinsic evidence as to whether a

common term has a special meaning in the relevant field. For a term without a special art-recognized meaning (*e.g.*, "between"), the judge may not need to consult any extrinsic source. Nonetheless, even with such non-technical terms, consultation of dictionaries may play a role in resolving disputes about ordinary meaning of terms not defined by the specification. So, while dictionary evidence does not set the baseline meaning of a claim term, the objectivity of dictionary evidence may provide a useful tool in weighing the parties' contentions as to ordinary meaning.

With technical terms, the person of ordinary skill has an understanding of the art-recognized meaning that the judge may typically lack. Therefore, the judge may reasonably seek to replicate – put on the appropriate "viewing glass" – by consulting extrinsic evidence to aid in the review of the intrinsic evidence. Judges should have discretion to consider extrinsic evidence, including expert testimony and technical dictionaries, when interpreting claims, especially technical terms of art. *See e.g. Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340 (Fed. Cir. 2004) (construing "headers" in the computer context).

If considered, the extrinsic evidence, including dictionaries, should always be considered for the purpose of elucidating the intrinsic evidence and not for the purpose of establishing a presumptive meaning of claim terms without reference to the intrinsic evidence. *See Markman*, 52 F.3d at 981; *see also Alloc. Inc. v. I.T.C.*, 342 F.3d 1361 (Fed. Cir. 2003) ("[A] court must resist relying on any of these sources [intrinsic and extrinsic] in a vacuum because they each influence the understanding of one of skill in the art at the time of invention. . . ."). "While extrinsic evidence can shed useful light on the relevant art – and thus

better allow a court to place itself in the shoes of a person of ordinary skill in the art – the 'intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.'" *Vanderlande*, 366 F.3d at 1318.

The very nature of a patent as a legal document demands that the specification, rather than evidence extrinsic to the patent like dictionaries, serve as the primary source for determining its legal scope. A "patent is a fully integrated written instrument." *Markman*, 52 F.3d at 978. For that reason, claim construction is "a necessarily sophisticated analysis of the whole [patent] document required by the standard construction rule that a term can be defined only in a way that comports with the instrument as a whole." *Markman*, 517 U.S. at 389.

C. Other Doctrines Which Assist in Arriving at and Confirming the Proper Construction of a Claim Term

Where ambiguity remains after the review of the intrinsic evidence, aided by extrinsic evidence where needed, application of other doctrines, such as claim differentiation and construction to preserve validity, become appropriate considerations to aid in determining the meaning a person of ordinary skill in the art would give the claim term. For example, "[i]t is settled law that when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim in determining either validity or infringement." *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1122 (Fed. Cir. 1985) (*en banc*). However, reliance on claim differentiation should be reserved for those situations where the review of the intrinsic and extrinsic evidence fails to yield a single clear definition. This prevents claim

differentiation from improperly "overshadow[ing] the express and contrary intentions of the patent draftsman." *See Hormone Research Foundation. Inc. v. Genentech, Inc.*, 904 F.2d 1558 (Fed. Cir. 1990).

Similarly (and in response to this Court's question (5)), in seeking the meaning of a truly ambiguous claim term (perhaps where several different definitions of a term could reasonably apply), competitors and the public should expect such terms to be construed in a manner that sustains the validity of the patent claim. Reliance on this doctrine comports with the statutory presumption of patent validity in 35 U.S.C. § 282. Yet, reliance on the doctrine should be limited to those situations where more than one interpretation is otherwise reasonable, but one interpretation would render the claim invalid. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 914 (Fed. Cir. 2004). As this Court noted in *Generation II Orthotics Inc. v. Med. Tech. Inc.*, 263 F.3d 1356, 1365 (Fed. Cir. 2001), "claims can only be construed to preserve their validity where the proposed claim construction is 'practicable,' is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims."

Finally, if a disputed term lacks a customary meaning, and was essentially created by the patentee (but not defined in the specification or prosecution history), its meaning should be derived from the context of the patent, but construed narrowly against the patent drafter, in view of the patentee's failure in his obligation to clearly define the term. *See J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1568 (Fed. Cir. 1997). As this Court has stated, "[w]here there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at

least entitled to the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning." *See Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996).

III. The Tension Between Proper Use of the Specification and Improper Reading in of Limitations

Our second issue – how the specification should properly be used to interpret claims without impermissibly importing limitations into the claims – relates to this Court's question (3). As this Court noted in *Markman*, "[t]he written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." 52 F.3d at 980. The *Texas Digital* court's motivation for advocating starting with dictionaries rather than the intrinsic evidence was the frequent mistake of impermissibly importing limitations from the specification. *See Texas Digital*, 308 F.3d at 1204. Despite the government's recommendation to scale back the use of dictionaries as the baseline for claim meaning, the government, like *Texas Digital*, recognizes that courts conducting claim construction face a great challenge navigating the shoals between properly relying on the specification and going too far and improperly importing limitations from it. "Fairness and the public notice function of the patent law require courts to afford patentees the full breadth of clear claim language, and bind them to it as well." *Tate Access Floors, Inc. v. Interface Architectural*, 279 F.3d 1357, 1367 (Fed. Cir. 2002). Typically, these competing policy concerns form the tension behind a determination whether to limit or broaden a claim term in view of the specification, even where the specification has not explicitly defined the term.

Recently, in *Liebel-Flarsheim*, 358 F.3d at 904, Judge Bryson described the "fine line" between the competing axioms that claims be read in view of the specification, and that limitations not be imported from the specification into the claims. He aptly observed that "[a]lthough parties frequently cite one or the other of these axioms to us as if the axiom were sufficient, standing alone, to resolve the claim construction issues we are called upon to decide, the axioms themselves seldom provide an answer, but instead merely frame the question to be resolved." *Id.*

Additional guidance by this Court on the issue could assist the district courts in resolving this tension. As a general matter, courts should be less inclined to infer a more narrow definition of a disputed claim term from the specification if a person of ordinary skill in the art would consider the feature relied on from the specification "exemplary" or insignificant to the essence or primary purpose of the invention. As this Court in *Alloc* phrased it, the balance between construing in light of the specification and impermissibly importing limitations, "turns on how the specification characterizes the claimed invention." 342 F.3d at 1370. This Court has attempted to interpret claims to encompass a feature that the specification describes as essential to the invention, or that the specification used to distinguish the prior art. For example, in *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1344 (Fed. Cir. 2000) and in *Wang Labs. v. America Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999), this Court held that claims cannot be construed as encompassing prior art that was distinguished in the specification and disclaimed during prosecution. *Toro Co. v. White Consolidated Indus.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999) illustrates a claim interpretation consistent with a feature

emphasized in the specification "as important to the invention."

A merely exemplary feature, because of its *exemplary* status, should not be read into claims whose words do not include that feature. By way of illustration, where the specification describes a feature, not found in the words of the claims, only to fulfill the statutory best mode requirement, the feature should be considered exemplary, and the patentee should not be unfairly penalized by the importation of that feature into the claims. A person of ordinary skill may also consider a feature merely exemplary where "nothing in the written description indicates that the invention is exclusively directed toward" the feature or suggests that embodiments without it are outside the scope of the invention. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1297, 1305 (Fed. Cir. 2003). However, if the specification "as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment," then defining a claim term in accordance with that limitation would be appropriate. *Alloc*, 342 F.3d at 1370.

IV. Deference

Our third issue (question (7)) concerns whether this Court owes any deference to district courts' claim construction decisions. Construing *Markman* and adhering to its prior position, this Court held in *Cybor* that claim construction is a matter of law reviewed *de novo* on appeal. *Cybor*, 138 F.3d at 1456. In our view, Judge Bryson correctly articulated that this Court should "approach the legal issue of claim construction recognizing that with respect to certain aspects of the task, the district court

may be better situated than [the Federal Circuit is], and that as to those aspects [this Court] should be cautious about substituting [its] judgment for that of the district court." *Cf.*, *Ornelas v. United States*, 517 U.S. 690, 699 (1996) (holding that reasonable suspicion and probable cause determinations are reviewable *de novo* but that "a reviewing court should take care both to review findings of historical fact only for clear error and to give due weight to inferences drawn from those facts by resident judges and local law enforcement officers"). A district court's consideration of live testimony relating to claim construction comprises one of the few examples where deference is appropriate.

The uncertainty resulting from this Court's high reversal rate on claim construction has generated concern, and has resulted in more claim construction appeals with more terms at issue. *See e.g.* Polk Wagner & Lee Petherbridge, Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance, 152 U. Pa. L. Rev. 1105, 1107 (2004); Joseph Scott Miller & James A. Hilsenteger, The Proven Key: Roles and Rules for Dictionaries at the Patent Office and the Courts, (unpublished manuscript, available at http://papers.ssrn.com/sol3/papers.cfrn?abstract_id=577262) (noting a sharp increase in claim construction appeals post-*Markman*); see *also Cybor*, 138 F.3d at 1476 (Rader, J., dissenting in part) (referring to the Court's "near 50%" reversal rate as "the worst possible"). Not only have the number of appeals on claim construction increased, but many include numerous disputed claim terms. *See e.g. Texas Digital*, 308 F.3d 1193 (nine terms); *Superguide Corp. v. DirectTV Ent.*, 358 F.3d 870 (Fed. Cir. 2004) (ten phrases). Moreover, many of these appeals come from summary judgment rulings, and often the record may

not yet be fully developed. *See e.g. AFG Industries, Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1375 (Fed. Cir. 2004) (Newman, J., dissenting) (dissenting from the panel's reversal of summary judgment and remand "for the third time on the issue of claim construction with respect to the claim term 'layer'"). Thus, it is not surprising that in a given case, *de novo* review of the interpretations of the multiple disputed claim terms, typically on a limited record, often yields some ground for reversal.

These problems should be addressed by this Court providing additional guidance on general principles of claim construction. Such additional guidance will likely generate more consistent and well-reasoned district court decisions. Under *de novo* review, a district court's claim construction stands or falls on such persuasiveness. *See Cybor*, 138 F.3d at 1462 (Plager, J., concurring) ("Th[e] weight [given to a trial judge's view] may vary depending on the care, as shown in the record, with which that view was developed, and the information on which it is based").

As this Court has recognized in an analogous context, "our *de novo* posture essentially repeats the Court of International Trade's review [of International Trade Commission determinations] for substantial evidence; however, 'we will not ignore the informed opinion of the Court of International Trade.'" *ALTX, Inc. v. United States*, 370 F.3d 1108, 1116 (Fed. Cir. 2004). A similar approach should be taken with respect to a district court's claim construction, so that rather than starting from a "clean slate," this Court gives due consideration to a persuasive claim construction by the district court and accords due weight to its evaluation of any live testimony on this issue.

CONCLUSION

In summary, to strike the appropriate balance between the public notice function of claiming and fairness to the patentee, the United States advocates the foregoing approach to claim construction and the review thereof.

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Respectfully submitted,

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RULE 32(a)(7)(c) CERTIFICATE OF COMPLIANCE

I certify pursuant to Fed. R. App. Proc. 32(a)(7) that the foregoing BRIEF OF THE UNITED STATES AS *AMICUS CURIAE* complies with the word limitation. The total number of words in the foregoing brief is 4,996 words as calculated by the Word Perfect word processing program used to prepare the brief.

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